## EXHIBIT 3



## AD BERGERARD CHANNES CHANNED ROLL

## TO ALL TO WHOM THESE; PRESENTS; SHALL; COME;

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office

January 31, 2020

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS OF:

APPLICATION NUMBER: 15/862,016

FILING DATE: January 04, 2018 **PATENT NUMBER: 10,028,740 ISSUE DATE:** *July 24, 2018* 

By Authority of the

**Under Secretary of Commerce for Intellectual Property** and Director of the United States Patent and Trademark Office

HOLLEY Certifying Officer

JOINT EXHIBIT

JTX-011

Case No. 1:16-cv-00570-RGA



January 4, 2018

Street Address Fish & Richardson P.C. 3200 RBC Plaza 60 South Sixth Street Minneapolis, MN 55402

Mail Address P.O. Box 1022

Minneapolis, MN 55440-1022

612 335 5070 main 877 769 7945 fax

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

Attorney Docket No.: 45335-0013002

Presented for filing is a new continuation patent application for prioritized examination of:

Inventor(s): NATHAN C. MOSKOWITZ, MOSHEH T. MOSKOWITZ AND AHMNON D. MOSKOWITZ

Title: HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH

INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL

**FUSION** 

Enclosed are the following papers, including those required to receive a filing date under 37 CFR 1.53(b):

	<u>Pages</u>
Specification	21
Claims	1
Abstract	1
Drawing(s)	33

## Enclosures:

- Application Data Sheet, 9 pages.
- Power of Attorney, 2 pages.
- Certification and Request for Prioritized Examination (Track I), 2 page

The applicant claims small entity status under 37 CFR 1.27.

Basic Filing Fee	\$70
Search Fee	\$300
Examination Fee	\$360

fr.com



## **Commissioner for Patents**

January 4, 2018

Publication fee	\$0		
Track I processing fee	\$70		
Track I prioritized examina	ation fee		\$2000
Total Claims 20	over 20	0 x \$40	\$0
Independent Claims 2	over 3	0 x \$210	\$0
Fee for Multiple Depender	nt claims		\$0
Application size fee for eac Total Sheets	\$0		
Surcharge for late filing fer or declaration	\$70		
Total Filing fee			\$2870

The total filing fee is being paid concurrently on the Electronic Filing System (EFS) by deposit account authorization. Apply any other required fees or any credits to Deposit Account No. 06-1050, referencing the attorney docket number shown above.

I hereby authorize the USPTO to communicate in response to email communications from the undersigned and practitioners under Customer No. 26191 in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via email. I understand that a copy of these communications will be made of record in the application file. (MPEP 502.03).

If this application is considered to be incomplete, or if a telephone conference would otherwise be helpful, call the undersigned at (612) 337-2538.

Send all correspondence to:

26191 Customer Number

Respectfully submitted,

/Stuart A. Nelson/

Stuart A. Nelson

Registration No. 63,947



Commissioner for Patents January 4, 2018

Enclosures SWN/aur 61614449.doc

Approved for use through 04/30/2017. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	45335-0013002			
Appiication vo	ita difeet 37 GFK 1.70	Application Number				
Title of Invention HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION						
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.  This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.						

## Secrecy Order 37 CFR 5.2:

	$_{\lnot}$ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursu	ant to
L	37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)	

Inventor Information:							
Inventor 1					Re	anove	
Legal Name	••••••						
Prefix Given Name	Middle Name	e		Family N	ame		Suffix
- Nathan	C.			Moskowitz	10000000000000000000000000000000000000		-
Residence Information (Select One	) ● US Residency	n US Resi	dency	Activ	e US Military Service	bood	
City Rockville	State/Province	MD	Country	of Resid	encė	US	
	•	!88-					
Mailing Address of Inventor:							
Address 1 212 North Adams Street							
Address 2							
City Rockville		St	ate/Provi	nce	MD		
Postal Code 20850		Country	yi l	JS			
Inventor 2							
Legal Name							
Prefix Given Name	Middle Name	e		Family N	ame		Suffix
✓ Mosheh	Τ.		Moskowitz				-
Residence Information (Select One	)   ÚS Residency	No	n US Resi	dency	Activ	e US Military Service	
City Rockville	State/Province	MD	Country	of Resid	encė	US	
Mailing Address of Inventor:			***************************************				
Address 1 212 North A	dams Street				***************************************		
Address 2		***************************************	***************************************				
City Rockville		St	ate/Provi	nce	MD		
Postal Code 20850	20850 Country i US						
Inventor 3							
Legal Name							
Prefix Given Name	Middle Name	e		Family N	ame		Suffix
<b>√</b> Ahmnon	b.			Moskowitz	10000000000000000000000000000000000000		<b>-</b>
Residence Information (Select One	)   US Residency	No	n US Resi	dency	Activ	e US Military Service	100000

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		Attorney Docket Number 453		45335-001300	335-0013002					
Application Da	ta Snec	et 3/ CFI	₹ 1./6	Application Number						
Title of Invention				EBRAL CUR OR SPINAL		NAIL-S	CREWS WITH IN	ITER-LOCKI	NG RIGID (	DR
City Rockville			State/	Province	MD	Count	ry of Residenc	:ė   US		
Mailing Address of	Invento	r:								
Address 1		212 North A	dams St.							
Address 2				***************************************				***************************************	***************************************	
City Rock	ville				Si	ate/Pro	vince M	)		
Postal Code		20850			Countr	yi	US			
All Inventors Mus generated within th					ormation	blocks	may be	Ad	ld	
Corresponder										
Enter either Custo For further inform				the Corres	ponden	ce Infor	mation section	ı below.		
An Address is	being p	rovided fo	r the co	rresponde	nce Info	rmation	of this applica	ation.		
Customer Numbe	r	26191								
Email Address		apsi@fr.cor	n				<i>F</i>	\dd Email	Remove	Email
Application I	nform	ation:								
Title of the Invent	ion	2		VSVERTEBI BLE RODS			R NAIL-SCREWS ION	WITHINIE	R-LOCKING	FRIGID
Attorney Docket I	lumber	45335-001	3002		s	mall Er	itity Status Cla	imed 🖂		
Application Type		Nonprovisi	onal							v
Subject Matter		Utility		***************************************			***************************************		***************************************	4
Total Number of E	)rawing	Sheets (if	any)	33		Sugges	ted Figure for	Publication	n (if any)	
Filing By Refe	ence	) .								
Only complete this secti application papers inclu provided in the appropr	ıding a spe	cification and	d any draw	ings are bein	ig filed. An	y domest	tic benefit or forei	gn priority inf	ormation mu ormation").	st be
For the purposes of a fili		nder 37 CFR 1	.53(b), the	description a	and any dr	awings of	the present appli	cation are rep	naced by mis	
reference to the previou	ing date ur Isly filed ap	oplication, su	bject to co	nditions and	requireme		CFR 1.57(a).		<u> </u>	i_
	ing date ur Isly filed ap	oplication, su	bject to co		requireme		CFR 1.57(a).	cation are rep ual Property /	<u> </u>	Country
reference to the previou Application number o	ing date ur Isly filed ap	oplication, su	bject to co	nditions and	requireme		CFR 1.57(a).		<u> </u>	i - Country
reference to the previou Application number o	ing date ur isly filed ap f the previo	oplication, su	bject to co	nditions and	requireme		CFR 1.57(a).		<u> </u>	Country
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Annlication Na	ita Sheet 37 CFR 1.76	Attorney Docket Number	45335-0013002			
_ Application of	ita director of it i.iu	Application Number				
Title of Invention	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION					

## Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.							
Please Select One:	◆ Customer Number	US Patent Practitioner	Limited Recognition (37 CFR 11.9)				
Customer Number	26191						

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate

## Domestic Benefit/National Stage Information:

National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78. When referring to the current application, please leave the "Application Number" field blank. Remove **Prior Application Status** Pendina Filing or 371(c) Date **Application Number** Continuity Type **Prior Application Number** (YYYY-MM-DD) Continuation of 12957776 2010-12-01 **Prior Application Status** Patented Remove Issue Date Application Prior Application Filing Date Continuity Type Patent Number Number Number (YYYY-MM-DD) (YYYY-MM-DD) 12471340 12957776 Continuation in part of 2009-05-22 8734516 2014-05-27 **Prior Application Status** Patented Remove Issue Date Prior Application Application Filing Date Continuity Type Patent Number Number (YYYY-MM-DD) (YYYY-MM-DD) Number 12471340 Continuation in part of 12054335 2008-03-24 7972363 2011-07-05 **Prior Application Status** Patented Remove Issue Date Application Prior Application Filing Date Continuity Type Patent Number (YYYY-MM-DD) Number Number (YYYY-MM-DD) 12054335 Continuation in part of 11842855 2007-08-21 7942903 2011-05-17 **Prior Application Status** Patented Remove Issue Date Prior Application Filing Date Application Continuity Type Patent Number (YYYY-MM-DD) Number Number (YYYY-MM-DD) 11842855 11536815 2006-09-29 7846188 2010-12-07 Continuation in part of

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Application Data Sheet 37 CFR 1.76				Attorney Docket Number			45335-0013002		
Application		Application Number							
Title of Invention HORIZONTAL-TRANSVERTEBR JOINTED FLEXIBLE RODS FOR							REWS WI	TH INTER-LOCK	(ING RIGID OR
Prior Application Status Patented				***************************************				Day	nove
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Application Number	Conti	nuity Type	Pri	or Applica Number	tion	Filing Da (YYYY-MM		Patent Number	Issue Date (YYYY-MM-DD)
11536815	Continuat	ion in part of 🔻	1120	18644		2005-08-23		7704279	2010-04-27
Prior Application Status Expired				¥		Remove			
Application Number Continuity 1		Туре		Prior Application Number (YYYY-MM-DI		• •			
12957776		Claims benefit	of pro	visional	v	60670231	2005-04-12		
Prior Application	n Status	Expired			Ŧ		Remove		
Application Number Continuity Type		Туре		Prior Application Number		1 -	Filing or 371(c) Date (YYYY-MM-DD)		
12957776 Claims benefit of provisional			visional	¥	61265752		2009-12-01		
1	Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.								

## Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)<sup>1</sup> the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number

Country<sup>1</sup>

Filing Date (YYYY-MM-DD)

Access Code<sup>1</sup> (if applicable)

Add button.

# Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

	This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also
	contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March
П	16, 2013.
	NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March
	16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Annlication Na	ta Sheet 37 CFR 1.76	Attorney Docket Number	45335-0013002		
_ Application Do	III OHEEL OF OH N 1.70	Application Number			
Title of Invention	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION				

## **Authorization or Opt-Out of Authorization to Permit Access:**

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant <u>must opt-out</u> of the authorization by checking the corresponding box A or B or both in subsection 2 below.

<u>NOTE</u>: This section of the Application Data Sheet is <u>ONLY</u> reviewed and processed with the <u>INITIAL</u> filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

- 1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)
- A. <u>Priority Document Exchange (PDX)</u> Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby <u>grants the USPTO authority</u> to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h) (1).
- B. <u>Search Results from U.S. Application to EPO</u> Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby <u>grants the USPTO authority</u> to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

- 2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)
   A. Applicant <u>DOES NOT</u> authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.
- B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

**NOTE:** Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	45335-0013002			
		Application Number				
Title of Invention	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	ORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR DINTED FLEXIBLE RODS FOR SPINAL FUSION				

## **Applicant Information:**

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.								
Applicant 1				Remove				
If the applicant is the inventor (of The information to be provided 1.43; or the name and address who otherwise shows sufficient applicant under 37 CFR 1.46 (a proprietary interest) together will identified in this section.	in this section is the nar of the assignee, person proprietary interest in the issignee, person to who	me and address to whom the in ne matter who is m the inventor i	of the legal ventor is uno the applica s obligated t	representat der an obligant under 37 to assign, or	ive who is the a ation to assign CFR 1.46. If th person who ot	applicant under 37 CFR the invention, or person e applicant is an herwise shows sufficient	t	
<ul><li>Assignee</li></ul>	Legal Re	Representative under 35 U.S.C. 117			Joint	Joint Inventor		
Person to whom the invento	r is obligated to assign.		Person who shows sufficient proprietary interest					
If applicant is the legal repre	sentative, indicate the	e authority to f	ile the pate	nt applicat	ion, the inven	tor is:		
					w			
Name of the Deceased or Lo	egally Incapacitated I	nventor:						
If the Applicant is an Organization check here.								
Prefix Gi	Given Name Middle Nam		e Family Name		ame	Suffix		
va	than	C.	Moskowitz				¥	
Mailing Address Information For Applicant:								
Address 1	212 North Adams Stre	et						
Address 2							******	
City Rockville			State/Province		MD			
Country US			Postal Code 20		20850	20850		
Phone Number			Fax Number					
Email Address								
Additional Applicant Data may be generated within this form by selecting the Add button.  Add  Add								

## **Assignee Information including Non-Applicant Assignee Information:**

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Application Data Sheet 37 CFR 1.76		Attorney Doo	ket Number	Number 45335-00130		3002	
		Application N	lumber				
Title of Invention HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION						CKING RIGID OR	
Assignee 1							
application publicat	tion. An assig pplicant. For a	e information, includin nee-applicant identifie an assignee-applicant	d in the "Applica	ant Information	ı" section will	appear on the	
						F	Remove
If the Assignee	or Non-Appl	icant Assignee is ar	organization	check here.			
Prefix	Gi	ven Name	Middle Name		Family Na	me	Suffix
	<b>*</b>						-
Mailing Address	Informatio	n For Assignee in	cluding Non-A	Applicant As	signee:		
Address 1							
Address 2							
City			State/Province		ince		
Country			Postal Code				
Phone Number			Fax Number		er		
Email Address							
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.							
Signature: Remove							
NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).  This Application Data Sheet must be signed by a patent practitioner if one or more of the applicants is a juristic entity (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, all joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of all joint inventor-applicants.  See 37 CFR 1.4(d) for the manner of making signatures and certifications.							
Signature /Stuart A. Nelson/				Date (YYYY-MN		YYY-MM-DI	D) 2018-01-04
First Name S	rst Name Stuart A. Last Name Nelson F			Registra	Registration Number 63,947		
Additional Signature may be generated within this form by selecting the Add button.  Add  Add							

## 

PTO/AIA/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Application Data Sheet 37 CFR 1.76		Attorney Docket Number	45335-0013002	
			Application Number		
	Title of Invention	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION			

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

## **Privacy Act Statement**

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
- A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m)
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

# HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION

[0001] This application is a Continuation-In-Part Application of co-pending Application Serial No. 12/471,340 filed on May 22, 2009, which is a Continuation-In-Part of co-pending Application Serial No. 12/054,335 filed on March 24, 2008, which is a Continuation-In-Part of Application Serial No. 11/842,855, filed on August 21, 2007, which is a Continuation-In-Part of Application Serial No. 11/536,815, filed on September 29, 2006, which is a Continuation-In-Part of Application Serial No. 11/208,644, filed on August 23, 2005, and this application also claims priority under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 60/670,231, filed on April 12, 2005, and U.S. Provisional Application No. 61/265,752, filed on December 1, 2009; the entire contents of all of the above identified patent applications are hereby incorporated by reference in their entirety.

#### FIELD OF DISCLOSURE

[0002] The present invention relates to a unique universal horizontal-transvertebral curvilinear nail-screw (HTCN) and to a method of applying such an HTCN to the spine, whereby a series of NTCN's, according to the exemplary embodiments, can be implanted into adjacent vertebrae can be inter-connected with either rigid or flexible jointed rods, fusing two or more adjacent vertebral bodies together thereby achieving either rigid or flexible fusion, respectively, and thus obviating the need for pedicle screw fixation in many but not all cases. The exemplary embodiments also can be used to salvage and/or extend pre-existing pedicle screw fusions.

#### BACKGROUND

The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in related applications Serial No. 12/054,335 filed on March 24, 2008, Serial No. 11/842,855, filed on August 21, 2007, Serial No. 11/536,815 filed on September 29, 2006, and Serial No. 11/208,644 filed on August 23, 2005, the contents of which are hereby incorporated by reference in their entirety. Conventionally, the majority of posterior and anterior spinal fusion surgical techniques are typically supplemented with the posterior placement of adjacent vertebral trans-pediclar screws.

[0004] Complications of pedicle screw placement in the spine include misplaced screws with neural and/or vascular injury, excessive blood loss, prolonged recovery, incomplete return to work, and excessive rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive, and stereotactic CT image-guided technology, imperfectly address some but not all of these issues.

#### SUMMARY

[0005] The present invention recognizes the aforementioned problems with conventional apparatus and solves these problems.

[0006] Herein described are exemplary embodiments of novel HTCNs which are implanted and embedded within adjacent vertebral bodies using a lateral horizontal side-to-side-trajectory avoiding the pedicles entirely, and thereby avoiding all the risks associated with the placement of transpedicular vertebral screws. Direct non-transpedicular placement of HTCNs into the vertebral bodies, according to the exemplary embodiments, is possible because the HTCN is curved, and thus, can achieve horizontal transvertebral access, which is not possible by conventional straight screws/nails. Likewise, the inter-connection of HTCNs with either rigid rods, or multiple embodiments of jointed flexible rods, can achieve rigid or flexible fusion, respectively.

[0007] The exemplary embodiments of a Horizontal transvertebral curvilinear nails (HTCN) can provide a segmental vertebral spinal fusion having a strength that is equal to or greater than a strength of conventional pedicle screws without the complications arising from conventional pedicle screw placement, which include misplacement with potential nerve and/or vascular injury, violation of healthy facets, and possible pedicle destruction. By placing HTCNs horizontally across the vertebral body, and not into the vertebral bodies via the transpedicular route, thereby excluding the posterior spinal column, the exemplary embodiments can preserve healthy facet joints and pedicles. The exemplary embodiments of HTCNs are designed with predetermined curved angles to avoid laterally exiting nerve roots. Furthermore, with respect to patients who already have had pedicle screws, with concomitant pedicular destruction, placement of HTCNs according to the exemplary embodiments can be employed as a salvage procedure achieving segmental fixation without having to engage additional rostral and caudal vertebrae transpedicularly, unnecessarily lengthening a spinal fusion, and adding more operative risk per fused level.

[0008] Furthermore, as a result of the orientation and length of the HTCNs according to the exemplary embodiments, multiple level fusions can be easily performed.

[0009] For example, exemplary embodiments are directed to one or more HTCNs, one or more interconnecting rigid rods, and one or more interconnecting jointed flexible rods. The HTCN can include a nail/screw which is precurved in multiple angles (e.g., a plurality of predetermined angles), for example, that take into account a safe trajectory upon insertion into the lateral posterior vertebral body beneath the pedicle and spinal canal, through the transverse process (or lateral to it), whose entry point and trajectory avoids exiting/traversing nerve roots from the spinal canal. The connecting rod can include a solid rod which can achieve rigid fusion. The embodiments of the connecting rod can include one or more flexible rods. For example, the flexible rods can include side to side, or head to head ball-socket joints that can allow multiple degrees of freedom of movement. The exemplary embodiment of the rods can be locked onto rostral and caudal

vertebral HTCNs via locking mechanisms. In an exemplary embodiment, all of the rods can be locked onto rostral and caudal vertebral HTCNs via locking mechanisms.

[0010] Another exemplary embodiment is directed to a method of inserting a HTCN laterally into the vertebral body. The method can include, for example, either direct, fluoroscopic, or navigational image guidance visualization of the transverse process to determine the initial entry point through the transverse process (or lateral, caudal or cephalad to it), and its curvilinear trajectory to the vertebral, lateral, sub-pedicular, subcanalicular lateral entry point into the vertebral body.

[0011] Exemplary methods of interlocking sequential HTCNs with rigid or jointed rods and their interlocking connectors are described herein. Once the surgeon is satisfied with the position and placement of the HTCNs either in unilateral or bilateral adjacent vertebral bodies, interconnecting rods that are either rigid, or jointed, can be attached and locked to the HTCNs achieving rigid or flexible fusion depending on the need of the patient and the choice of the surgeon.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0012]** The accompanying drawings are presented to aid in the description of embodiments of the invention and are provided solely for illustration of the embodiments and not limitation thereof.

[0013] Figures 1A-H illustrate an exemplary embodiment of an HTCN solid-flat head embodiment I in lateral (Figure A), and en-face (Figure B) views, and lateral views of an exemplary embodiment of a threaded screw cap embodiment II (Figure C), an exemplary embodiment of a threaded nail body embodiment III (Figure D), an exemplary embodiment of a fish-hooked tail embodiment IV (Figures E and F), and an exemplary embodiment of a threaded tail/screw embodiment V (Figures G and H).

[0014] Figures 2A-D illustrate exemplary embodiments of an HTCN, embodiments (I-V), inserted bilaterally into two adjacent transparent vertebral bodies in top-oblique (Fig A), lateral (Figure B), axial (Figure C) and top (Figure D) views.

- [0015] Figures 3A-D illustrate exemplary embodiments of an HTCN, embodiments (I-V), inserted bilaterally into two adjacent non-transparent vertebral bodies in topoblique (Fig A), lateral (Figure B), axial (Figure C) and top (Figure D) views.
- [0016] Figure 4A illustrates exemplary embodiments of a rigid connecting rod-HTCN construct (Embodiment I) inserted bilaterally into two adjacent vertebral bodies in the superior oblique view
- [0017] Figure 4B illustrates an exploded view of the rigid connecting rod-HTCN construct (Embodiment I) of Figure 4A.
- [0018] Figures 4C, D and E illustrate lateral (Figure C), axial (Figure D), and top (Figure E) view of exemplary embodiments of a rigid connecting rod-HTCN construct (Embodiment I) inserted bilaterally into two adjacent vertebral bodies.
- [0019] Figure 5A illustrates exemplary embodiments of a ball-socket, side-side jointed connecting rod-HTCN construct (Embodiment II) in the superior- oblique view.
- [0020] Figure 5B illustrates an exploded view of the ball-socket, side-side jointed connecting rod-HTCN construct (Embodiment II) of Figure 5A.
- [0021] Figures 6A-D illustrate superior-oblique (Figure A), lateral (Figure B), axial (Figure C), and top (Figure D) view of exemplary embodiments of a ball-socket, side-side jointed connecting rod-HTCN construct inserted bilaterally into two adjacent vertebral bodies.
- [0022] Figure 7A illustrates exemplary embodiments of a ball- socket, head-head, jointed connecting rod-HTCN construct (Embodiment III) in the superior oblique view.
- [0023] Figure 7B illustrates an exploded view of the ball-socket, head-head jointed connecting rod-HTCN construct (Embodiment III) of Figure 7A.
- [0024] Figures 8A-D illustrate the superior-oblique (Figure A), lateral (Figure B), axial (Figure C), and top (Figure D) views of exemplary embodiments of a ball-socket, head-head jointed connecting rod-HTCN construct inserted bilaterally into two adjacent vertebral bodies.

# DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS OF THE INVENTION

[0025] Aspects of the invention are disclosed in the following description and related drawings directed to specific embodiments of the invention. Alternate embodiments may be devised without departing from the scope of the invention. Additionally, well-known elements of the invention will not be described in detail or will be omitted so as not to obscure the relevant details of the invention.

[0026] The word "exemplary" is used herein to mean "serving as an example, instance, or illustration." Any embodiment described herein as "exemplary" is not necessarily to be construed as preferred or advantageous over other embodiments. Likewise, the term "embodiments of the invention" does not require that all embodiments of the invention include the discussed feature, advantage or mode of operation.

[0027] With reference to FIGS. 1A-8D, exemplary embodiments of the invention will now be described.

## [0028] 1. THE MEDICAL DEVICE

**[0029]** Referring to FIGS. 1A-8D, the above described problems of the conventional art can be solved in the spine by horizontal transvertebral insertion into adjacent vertebral bodies either unilateral or bilateral HTCN-interconnecting rigid or flexible jointed connecting constructs according to the exemplary embodiments, thereby achieving rigid or flexible vertebral fusion/fixation.

[0030] For example, Figures 1A-H illustrate three-dimensional views of five different exemplary embodiments of a single HTCN which can be horizontally inserted unilaterally into a single vertebra.

[0031] Figures 1A-B illustrate an exemplary embodiment of a solid flat-head HTCN 10 (embodiment I). The HTCN 10 can include a single piece construct manufactured out of any type of bio-compatible material. The HTCN 10 can include a body 12 having a

sharp pointed tip 14 and a head 16. The HTCN 10 can include a geometry that is curvilinear, allowing its sharp pointed tip 14 to be posteriorly or laterally, or anteriorly introduced, and to penetrate the mid lateral aspect of a vertebral body. The head 16 can include a flat head that provides a surface which can be tamped upon by any variety of instruments in order to insert the pointed tip 14 (e.g., tail portion) and a portion of the body 12 into the core of the vertebral body. In this example, the orientation of the HTCN 10 within the vertebral body is horizontal, as opposed to trans-pedicular. Hence, the exemplary embodiment allows a non-pedicular based posterior, lateral or anterior vertebral fusion.

threaded screw cap 16 (embodiment II). In this embodiment, the geometry of the HTCN 10 can be identical to the embodiment I described above. Rather than being one solid piece, the exemplary HTCN 10 can include two separate pieces or portions, such as a) a screw cap 16a, and b) the HTCN body 12 and portion (e.g., tail portion) with a pointed tip 14. The superior flat headed surface 16 of the HTCN 10 can include a central threaded perforation or opening 16b into which a threaded screw portion 17 of the cap 16a can be secured by threaded engagement or screwed into. The screw cap 16a can secure the HTCN 10 to the interconnecting rod locking devices (described in greater detail below).

[0033] Figure 1D illustrates an exemplary embodiment of an HTCN 10 having a body 12 includes a threaded head or portion 16d (embodiment III). In this embodiment, the upper outer surface of the head 16d is threaded to accept a screw cap 16c having internal corresponding threading. The HTCN 10 according to this embodiment can function similar to the embodiment II described above.

[0034] Figures 1E and F illustrate an exemplary embodiment of an HTCN 10 including a fish-hooked tail or portion 18 (embodiment IV). In this embodiment, the tail 18 of the HTCN 10 can include a series of radially arranged fish-hooks 20 to engage the cancellous core of the vertebral body. Figure 1F is an enlargement illustrating details of an exemplary embodiment of the radial fish-hook 18.

[0035] Figures 1G and H illustrate an exemplary embodiment of an HTCN 10 including a threaded tail-screw 22 (embodiment V). The threaded tail 22 can include threads 24 that can engage the cancellous core of the vertebral body. Figure 1H is an enlargement illustrating details of an exemplary embodiment the threads 24.

[0036] Other variations and embodiments of the HTCN 10 can include any other type of mechanism that allows insertion and immobility of the HTCN 10 into and within the vertebral body (bodies).

[0037] The angle and geometric configuration of the HTCN 10 also can be altered or varied in multiple manners. The HTCN 10 also can be manufactured in varying sizes with respect to length and width providing a selection from which to choose to address different sized vertebral bodies in the same and /or different patients.

100381 Figures 2A-D exemplarily illustrate the placement of a total of four HTCNs 10 into two adjacent transparent vertebral bodies in order to achieve their fusion, according to an exemplary method. A first HTCN 10 is inserted unilaterally into the right transparent vertebral body, a second HTCN 10 is inserted unilaterally into the left transparent vertebral body, a third HTCN 10 is inserted into the adjacent right transparent vertebral body, and a fourth HTCN 10 is inserted into the adjacent left transparent vertebral body. Two of the HTCNs 10 are lined up on the right, and two of the HTCNs 10 are lined up on the left. The initiating path of the curvilinear HTCNs 10 may begin posteriorly, laterally, or anteriorly, and the trajectory of the HTCN 10, for example, in all cases, is horizontal from its mid-lateral vertebral entry point to its final destination which is the relative inner center of the vertebral body. The HTCNs 10 are seen perforating the transverse processes. This is the estimated trajectory orientation for avoiding (e.g., necessary to avoid) exiting nerve roots. The entry point of the HTCN can be more medial, lateral, caudal or rostral to the transverse process. The initial position of insertion may be via a posterior, lateral or surgical approaches.

[0039] Figures 2A-D are transparent in order to appreciate the necessary HTCN trajectory, its position and orientation within the vertebrae, its entry point into the mid lateral vertebrae (Figure 2B) and its starting and destination points.

[0040] Figures 3A-D exemplarily illustrate the placement of a total of four HTCNs 10 into two adjacent non-transparent vertebral bodies 100 in order to achieve fusion of these two adjacent bodies. A first HTCN 10 is inserted unilaterally into the right non-transparent vertebral body 100, a second HTCN 10 is inserted unilaterally into the left non-transparent vertebral body 100, a third HTCN 100 is inserted into the adjacent right non-transparent vertebral body 100, and a fourth HTCN 10 is inserted into the adjacent left non-transparent vertebral body 100. In the exemplary embodiment illustrated in Figures 3A-D, two of the HTCNs 10 are lined up on the right, and two of the HTCNs 10 are lined up on the left. The path of the curvilinear HTCNs 10 begins posteriorly, and its trajectory is horizontal from its entry point into the mid lateral vertebral body 100 to its final destination which is the relative center of the vertebral body 100.

[0041] The HTCNs 100 are illustrated as perforating the transverse processes 102. Figures 3A-D illustrate an example of an estimated trajectory and orientation for avoiding (e.g., necessary to avoid) exiting nerve roots. In other embodiments, the entry point of the HTCN 10 can be more medial, lateral, caudal, or rostral to the transverse process 102. The initial position of insertion may be via posterior, lateral, or anterior surgical approaches.

[0042] Figures 3A-D exemplarily illustrate how the HTCNs 10 may appear to the surgeon during a hypothetical operation.

HTCN construct (Embodiment I) that can achieve rigid segmental fusion of two adjacent vertebral bodies 100. This exemplary embodiment can include two HTCNs 10 coupled together. This connection can be rigid or fixed in at least one degree of movement, or more than one degree of movement. As illustrated in the exemplary embodiment, the HTCNs 10 can be coupled together by a rigid HTCN connecting bar 30, which can be threaded on either end, two connecting bar links 32, which can couple the bar 30 to each of the two HTCNs 10, and two tightening nuts 34 on the outsides of the connecting bar links 32, which can secure the connecting bar links 32 and bar 30 to the HTCNs 10. The connecting bar links 32 can include a first (upper) perforation (e.g., opening, through-hole,

etc.) 39 that receives or engages a portion of the connecting bar 32, and a second (lower) perforation (e.g., opening, through-hole, etc.) 38 that receives or engages a portion of the HTCN 10, such as the head 16 of the HTCN 10. The HTCNs 10 are inserted into the second (lower) perforations 38 of the connecting bar link 32. In this manner, when the HTCNs 10 are secured to the vertebral bodies 100, each of the heads 16 of the HTCNs 10 is placed into a second (lower) perforation 38 of each of the two adjacent connecting bar links 32. This exemplary embodiment can include an HTCN 10 according to any of the exemplary embodiments (I-V) described above, as well as other arrangements.

[0044] The threaded rigid HTCN connecting bar 30 then can be implanted into the superior perforations (first or upper perforations) 39 of the connecting link 32 such that the threaded ends of the connecting bar 30 are disposed on the outside of the connecting links 32. A threaded tightening nut 34 can be secured to either or both ends of the connecting bar 30. In this manner, the exemplary embodiment can securely and effectively link two adjacent HTCNs 10 together in a rigid manner, thereby effectively achieving a rigid segmental fusion of two adjacent vertebrae.

[0045] Figures 4A-E exemplarily illustrate the implantation of these constructs into both the left and right sides of the spine.

bar 30. However, one or ordinary skill in the art will recognize that more than two THCNs 10 can be coupled to each connecting bar 30. Furthermore, the threading on the connecting bar 30 is not limited to the illustrated embodiment and can extend along a portion or all of the length of the connecting bar 30. For example, in an alternative embodiment, three or more nuts 34 can be secured to the threaded connecting bar 30 to secure two or more connecting bar links 34 (e.g., three or four links 34, etc.) to the connecting bar 30, such that two or more HTCNs 10 (e.g., three or four HTCNs 10, etc.) can be coupled to the same connecting bar 30. The diameter of the connecting bar 30 is illustrated as being uniform along a length of the connecting bar 30. However, other embodiments are possible in which the diameter of the body of the connecting bar 30, the diameter of the threads, etc. can be different at different portions of the connecting bar

30. Other embodiments can include more than two connecting bar links 32, and more than two tightening nuts 34.

[0047] Figures 5A through 5B illustrate an exemplary embodiment of a plurality of HTCNs 10 coupled together with a flexible or movable connecting rod-HTCN construct (Embodiment II). For example, a ball and trough, side-side jointed connecting rod 40 can couple two or more HTCNs 10 together such that the HTCNs can move with respect to each other while being secured to each other. The connecting rod 40 can provide a flexible fusion or coupling (e.g., a movable coupling in at least one dimension) between the plurality of HTCNs 10.

In this embodiment, rather than using a horizontal rigid rod, such as the rod 30 in the embodiment illustrated in Figures 4A-E, the connecting rod 40 that connects two adjacent implanted HTCNs 10 can include two inter-locking components that allow for movement. The inter-locking components can include, for example: a) a first hemi-rod 44 having a distal end with a ball portion projecting from a side, and b) a second hemi-rod 42 having a distal end with an accepting trough (e.g. socket) projecting from its side. The first hemi-rod 44 can be coupled to the second hemi-rod 42 in a ball and socket manner.

[0049] The side to side interaction of the ball and trough components 44, 42 can provide a certain or predetermined degree of flexibility with motion or movement between the adjacent HTCNs 10 being coupled together. Hence, the exemplary embodiment can provide a flexible fusion or coupling between adjacent HTCNs 10.

This exemplary embodiment can include, for example, similar components as the embodiment I illustrated in Figures 4A-E. For example, two connecting bar links 32 and two or more tightening nuts 46 can be provided on either side of the two rod components 44, 42. The ends of the ball and trough rod components 44, 42 can be threaded 48 to receive or engage the nuts 46 to secure the connecting bar links 32 to the ball and trough rod components 44, 42, enable tightening of the constructs.

[0051] The connecting bar link 32 can include a first (superior, upper) perforation (e.g., opening, through-hole, etc.) 52 that receives or engages a portion of one of the rod

components 44, 42, and a second (inferior, lower) perforation (e.g., opening, throughhole, etc.) 50 that receives or engages a portion of the HTCN 10, such as the head 16 of the HTCN 10. The HTCNs 10 are inserted into the second (inferior, lower) perforations 50 of the connecting bar link 32. In this manner, when the HTCNs 10 are secured to the vertebral bodies 100, each of the heads 16 of the HTCNs 10 is placed into a second (lower) perforation 50 of each of the two adjacent connecting bar links 32. This exemplary embodiment can include an HTCN 10 according to any of the exemplary embodiments (I-V) described above, as well as other arrangements.

[0052] The threaded portions or ends of each of the rod components 44, 42 can be inserted into the first (upper) perforations 52 of the connecting link 32 such that the threaded ends 48 of each of the rod components 44, 42 are disposed on the outside of the connecting links 32. A threaded tightening nut 46 can be secured to the end of each of the rod components 44, 42. In this manner, the exemplary embodiment can securely and effectively link two adjacent HTCNs 10 together in a flexible or moveable manner, thereby effectively achieving a flexible or moveable segmental fusion of two adjacent vertebrae.

[0053] Figures 6A-D exemplarily illustrate the ball and trough, side-side jointed connecting rod-HTCN construct (Embodiment II) that can provide a flexible fusion inserted bilaterally into adjacent vertebral bodies of the spine. Any of the five disclosed exemplary embodiments of the HTCN 10 (embodiments I-V), as well as other arrangements, may be selected for these constructs to insert into two adjacent vertebral bodies 100. Once this is done, the threaded, ball and trough, side-to-side jointed HTCN connecting bar 40 (rod components 44, 42) then can be implanted into the superior perforations (upper perforations) 52 of the connecting link 32, with at least a part of the threaded portions 48 of the rod components 44, 42 protruding outside these connecting links 32. Then the threaded tightening nuts 46 can be secured to either threaded end 48 of the rod components 44, 42 of the connecting bar 40. This construct effectively links two adjacent HTCNs 10 together in a non-rigid manner, effectively achieving flexible segmental fusion of two adjacent vertebrae.

[0054] Figures 6A-D exemplarily illustrate the implantation of these constructs into both the left and right sides of the spine.

The exemplary embodiment is illustrated with two HTCNs 10 per connecting bar 40. However, in alternative embodiments, more than two THCNs 10 can be coupled to each connecting bar 40. Furthermore, the threading 48 on the connecting bar 40 is not limited to the illustrated embodiment. For example, in an alternative embodiment, three or more nuts 34 can be secured to the threaded connecting bar 40 to secure two or more connecting bar links 34 (e.g., three or four links 34, etc.) to the connecting bar 40, such that two or more HTCNs 10 (e.g., three HTCNs 10) can be coupled to the same connecting bar 40. Other embodiments can include more than two connecting bar links 32, and more than two tightening nuts 34.

[0056] Figures 7A and B illustrate another exemplary embodiment of a plurality of HTCNs 10 coupled together with a ball and trough, head-to-head jointed connecting rod-HTCN construct (Embodiment III) to provide a flexible (or moveable) segmental fusion between the HTCNs 10.

[0057] For example, rather than using a horizontal rigid connecting rod 30, or a side-to-side ball and trough connecting rod 40, this exemplary embodiment includes a connecting rod 60 that connects two adjacent implanted HTCNs 10 and that includes two (a pair of) inter-locking components including, for example: a) a first hemi-rod 64 having a distal end including a ball projecting from its head, and b) a second hemi-rod 62 having a distal end including an accepting trough (or socket) projecting from its head.

This exemplary embodiment can include, for example, similar components as the embodiment I illustrated in Figures 4A-6D. The connecting rod 60 can include two connecting bar links 66 and two tightening nuts 70 on either side of the two rod components 64, 62 of the rod components 64, 62 of the connecting bar 60. The ends of the ball and trough head-head rod components 64, 62 can be threaded 68 to enable securing and tightening of the nuts 70 to the bar links 66, thereby securing the connecting bar links 66 to the ball and trough rod components 64, 62, enable tightening of the constructs.

[0059] The connecting bar link 66 can include a first (superior, upper) perforation (e.g., opening, through-hole, etc.) 74 that receives or engages a portion of one of the rod components 64, 62, and a second (inferior, lower) perforation (e.g., opening, through-hole, etc.) 72 that receives or engages a portion of the HTCN 10, such as the head 16 of the HTCN 10. The HTCNs 10 are inserted into the second (inferior, lower) perforations 72 of the connecting bar link 66. In this manner, when the HTCNs 10 are secured to the vertebral bodies 100, each of the heads 16 of the HTCNs 10 is placed into a second (lower) perforation 72 of each of the two adjacent connecting bar links 66. This exemplary embodiment can include an HTCN 10 according to any of the exemplary embodiments (I-V) described above, as well as other arrangements.

The threaded portions or ends 68 of each of the rod components 64, 62 can be inserted into the first (upper) perforations 74 of the connecting link 66 such that at least a portion of the threaded ends 68 of each of the rod components 64, 62 are disposed on the outside of the connecting links 66. A threaded tightening nut 70 can be secured to the threaded end 68 of each of the rod components 64, 62. In this manner, the head-head to side interaction of the ball and trough can enable or provide a certain (or predetermined) degree of flexibility with respect to motion between two adjacent and secured HTCNs 10, and hence, can provide a flexible fusion.

[0061] Figures 8A-D illustrate an exemplary embodiment of the ball and trough, head-head jointed connecting rod-HTCN construct (Embodiment III) that can provide a flexible fusion inserted bilaterally into the spine. Any of the five exemplary embodiments of the HTCN 10 (I-V) illustrated in Figures 1A-3D, as well as other arrangements, may be selected for these constructs to insert into two adjacent vertebral bodies 100. Once this is done, the threaded ball and trough, head-head jointed HTCN connecting bar 60 then can be implanted into the superior perforations 74 of the connecting link 66, with at least a portion of the threaded portion 68 of the rod components 64, 62 protruding outside the connecting links 66. Then, the threaded tightening nuts 70 can be secured to either threaded end 68 of the rod components 64, 62 of the connecting bar 60. This exemplary embodiment can provide a construct that

effectively links two adjacent HTCNs 10 together in a non-rigid manner, effectively achieving flexible segmental fusion of two adjacent vertebrae.

[0062] Figures 8A-D exemplarily illustrate the implantation of these constructs into both the left and right sides of the spine.

[0063] All of the exemplary embodiments can be made of any biocompatible material, and can be manufactured in different sizes. The HTCNs 10 can be coupled together with various other interconnecting devices that can secured, either rigidly or non-rigidly, the HTCNs 10 together, and the embodiments are not limited to the exemplary embodiments illustrated in Figures 4A-8D.

## [0064] 2. SURGICAL METHOD

**[0065]** With reference again to Figures 1A-8D, exemplary methods and surgical steps for practicing one or more of the foregoing exemplary embodiments will now be described.

[0066] In practice, the HTCNs 10 are surgically implanted into two or more adjacent vertebrae, either unilaterally or bilaterally (see, e.g., Figures 2 and 3). The HTCNs 10 can be inserted using posterior, lateral, or anterior approaches. The HTCNs 10 can be inserted posterior through midline, or par midline approaches through opened, closed, endoscopic, or tubular techniques with or without fluoroscopic monitoring, or any other form of image guidance. The HTCNs 10 can be inserted through a lateral or anterior approach in likewise manner.

[0067] The surgeon can select an HTCN 10 according to any of the five HTCN embodiments (I-V) described herein, as well as other arrangements, for implantation (e.g., see Figure 1 A-H). Once two or more HTCNs 10 are inserted either unilaterally or bilaterally into adjacent vertebral bodies, then the surgeon can choose to connect two or more HTCNs 10 using, for example, the exemplary rigid HTCN connecting rod 30 for providing rigid segmental fusion (e.g., see Figure 4). Alternatively, the surgeon can choose to connect one or more HTCNs 10 using, for example, (a) a flexible connecting rod 40 to form a ball and trough, side to side, jointed flexible rod-HTCN construct

(embodiment II, Figures 5 and 6), or (b) a flexible connecting rod 60 to form a ball and trough, head to head, jointed flexible rod-HTCN construct (embodiment III), Figures 7 and 8.

The surgical procedure performed when choosing the rigid rod-HTCN construct (Embodiment I) begins with implantation of the HTCNs 10 into the lateral vertebral body 100 (e.g., Figures 2 and 3). One of the five embodiments of HTCNs 10, or other arrangements, can be chosen (e.g., Figure 1A-H). Next, the HTCNs 10 can be tapped/screwed into the vertebral body 100 using a tamp and/or screw driver, or other suitable tool or device. Fluoroscopy/x-ray/image guidance can be used to confirm the entry point into the mid vertebral body, as well as the inner core mid-vertebral destination of the tapered end (pointed tip 14) of the HTCN 10. With posterior implantation, the pointed tip 14 of the HTCN 10 will often, but not necessarily always, traverse and perforate the transverse process (processes) 102 en route to its entry point into the midlateral vertebral body 100. Once two or more adjacent HTCNs 10 are successfully implanted into two adjacent vertebral bodies 100, then the heads 16 of the HTCN 10 can be placed into the inferior perforations 38 of two adjacent connecting bar links 32 (e.g., see Figures 4A-E).

[0069] The threaded rigid HTCN connecting bar 30 then can be inserted into the superior perforations 39 of the adjacent connecting bar links 32 with its threaded ends 36 protruding out of these links 32 (Figures 4A-E). Next, the threaded tightening nuts 34 can be secured to either threaded end 36 of the connecting bar 30. This construct effectively links two adjacent HTCNs 10 together in a rigid manner effectively achieving rigid fusion of two adjacent vertebrae. In other embodiments, the HTCN 10 can include a screw cap 16a, 16c that is fastened and tightened to a threaded portion 16b, 16d of the body 12 of the HTCN 10 to secure the head 16 of the HTCN to the inferior perforation 38 of the connecting rod link 32.

**[0070]** With reference to Figures 1A-3D and 5A-6D, exemplary methods and surgical steps for practicing one or more of the exemplary embodiments of flexible connecting bar constructs will now be described.

[0071] An example of a method or surgical procedure performed when choosing the flexible, ball and trough, side-side, rod-HTCN construct (Embodiment II) begins with implantation of the HTCNs 10 into the lateral vertebral body 100 (Figures 2 and 3). One of five exemplary embodiments of HTCNS 10, or other suitable arrangement, can be chosen (Figures 1A-H). Next, the HTCNs 10 can be tapped/screwed into the vertebral body 100 using a tamp and/or a screw driver, or other suitable tool or device. Fluoroscopy/x-ray/image guidance can be used to confirm the entry point into the mid vertebral body, as well as the ultimate inner core mid-vertebral destination of the tapered end (pointed tip 14) of the HTCN 10. With posterior implantation, the pointed tip 14 of the HTCN 10 will often, but not always, traverse and perforate the transverse process (processes) 102 en route to the entry point of the HTCN 10 into the mid-lateral vertebral body 100. Other trajectories also can be used. Once two or more adjacent HTCNs 10 are successfully implanted into two adjacent vertebral bodies 100, then the heads 16 of the HTCN 10 can be placed into the inferior perforations 50 of two adjacent connecting bar links 36 (e.g., see Figures 5 and 6).

Interested into the superior perforations 52 of the adjacent connecting bar links 32 with at least a portion of the threaded ends 48 protruding out of these links 32 (Figures 5 and 6). One hemi-rod (ball) 44 is inserted into one connecting link 32, and the other hemi-rod (trough) 42 is inserted into the adjacent connecting link 32. The placement of the ball 44 against the trough 42 can be optimized for flexibility. Next, the threaded tightening nuts 46 are secured to either of the threaded ends 48 of the rod components 44, 42 of the hemi-connecting bars 40. These exemplary constructs can effectively link two adjacent HTCNs 10 together in a flexible manner effectively achieving rigid fusion of two adjacent vertebrae. With respect to the HTCN embodiments with screw caps 16a, 16c, once the construct is created, the screw caps 16a, 16c can be fastened and tightened to the superior ends 16b, 16d of the body 12 of the HTCNs 10 which protrude from outside the inferior perforations 50 of the connecting bar links 32, thereby securing the head 16 of the HTCN 10 to the inferior perforation 50 of the connecting bar links 32.

**[0073]** With reference to Figures 1A-3D and 7A-8D, exemplary methods and surgical steps for practicing one or more of the exemplary embodiments of flexible connecting bar constructs will now be described.

An example of a method or surgical procedure performed when choosing the [0074] flexible, ball and trough, head-head, rod-HTCN construct (Embodiment III) begins with implantation of the HTCNs10 into the lateral vertebral body100 (Figures 2 and 3). One of five exemplary embodiments of HTCNs 10, or other suitable arrangements, can be chosen (Figures 1A-H). Next, the HTCNs 10 are tapped/screwed into the vertebral body 100 using a tamp and/or a screw driver, or other suitable tool or device. Fluoroscopy/xray/navigational image guidance can be used to confirm the entry point into the mid vertebral body, as well as the ultimate inner core mid-vertebral destination of the tapered end (pointed tip 14) of the HTCN 10. With posterior implantation, the pointed tip 14 of the HTCN 10 will often, but not always, traverse and perforate the transverse process (processes) 102 en route to its entry point into the mid-lateral vertebral body 100. Other trajectories also can be used. Once two or more adjacent HTCNs 10 are successfully implanted into two adjacent vertebral bodies 100, then the heads 16 of the HTCN 10 are placed into the inferior perforations 72 of two adjacent connecting bar links 66 (e.g., see Figures 7 and 8).

The threaded flexible HTCN connecting bar 60 is then inserted into the superior perforations 74 of the adjacent connecting bar links 66 with at least a portion of the threaded ends 68 protruding out of these links 66 (Figures 7 and 8). One hemi-rod (ball) 64 is inserted into one connecting link 66, and the other hemi-rod (trough) 62 is inserted into the adjacent connecting link 66. The placement of the ball 64 against the trough 62 can be optimized for flexibility. Next, the threaded tightening nuts 70 can be secured to either threaded end 48 of the rod components 64, 62 of the hemi-connecting bar 60. This exemplary construct can effectively link two adjacent HTCNs 10 together in a flexible manner effectively achieving flexible segmental fusion of two adjacent vertebrae. With respect to the HTCN embodiments with screw caps 16a, 16c, once the construct is created, the screw caps 16a, 16c can be fastened and tightened to the superior

ends 16c, 16d of the HTCNs 10 which protrude from outside the inferior perforations 72 of the connecting bar links 66, thereby securing the head 16 of the HTCN 10 to the inferior perforation 72 of the connecting rod link 66.

The exemplary embodiments of the Horizontal Curvilinear Transvertebral [0076] Nail-screws (HTCNs) described herein can provide a segmental vertebral spinal fusion that has a strength that is equal to or greater than a strength provided by conventional pedicle screws without the complications arising from pedicle screw placement, which can include, for example, misplacement with potential nerve and/or vascular injury, violation of healthy facets, and possible pedicle destruction. By placing the exemplary HTCNs 10 horizontally across the vertebral body, and not into the vertebral bodies via the transpedicular route thereby excluding the posterior spinal column, then healthy facet joints and pedicles can be preserved. The exemplary HTCNs 10 can include predetermined curved angles to avoid laterally exiting nerve roots. Furthermore, with respect to patients who already have had pedicle screws, with concomitant pedicular destruction, the placement of the exemplary HTCNs 10 can be employed as a salvage procedure achieving segmental fixation without, for example, having to engage additional rostral and caudal vertebrae transpedicularly, unnecessarily lengthening a spinal fusion, and adding more operative risk per fused level.

[0077] Furthermore, because of the orientation and length of the exemplary HTCNs, multiple level fusions can be easily performed.

[0078] The present invention has been described herein in terms of several preferred embodiments. However, modifications and additions to these embodiments will become apparent to those of ordinary skill in the art upon a reading of the foregoing description. It is intended that all such modifications and additions comprise a part of the present invention to the extent that they fall within the scope of the several claims appended hereto.

[0079] Like numbers refer to like elements throughout. In the figures, the thickness of certain lines, layers, components, elements or features may be exaggerated for clarity.

[0080] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the specification and relevant art and should not be interpreted in an idealized or overly formal sense unless expressly so defined herein. Well-known functions or constructions may not be described in detail for brevity and/or clarity.

[0081] As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items. As used herein, phrases such as "between X and Y" and "between about X and Y" should be interpreted to include X and Y. As used herein, phrases such as "between about X and about Y." As used herein, phrases such as "from about X to Y" mean "from about X to about Y."

[0082] It will be understood that when an element is referred to as being "on", "attached" to, "connected" to, "coupled" with, "contacting", etc., another element, it can be directly on, attached to, connected to, coupled with or contacting the other element or intervening elements may also be present. In contrast, when an element is referred to as being, for example, "directly on", "directly attached" to, "directly connected" to, "directly coupled" with or "directly contacting" another element, there are no intervening elements present. It will also be appreciated by those of skill in the art that references to a

structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[0083] Spatially relative terms, such as "under", "below", "lower", "over", "upper", "lateral", "left", "right" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if the device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the descriptors of relative spatial relationships used herein interpreted accordingly.

## WHAT IS CLAIMED IS:

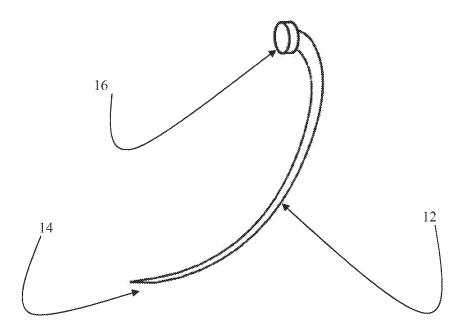
- 1. A horizontal-transvertebral curvilinear nail-screw (HTCN) comprising:
- a body portion having a first end and a second end, wherein the first end is opposed to the second end; and
  - a head at the first end of the body portion,
- wherein the body portion has a predetermined curvilinear shape and includes a pointed tip at the second end of the body portion.

Attorney Docket No.: 45335-0013002

## **ABSTRACT**

A horizontal-transvertebral curvilinear nail-screw (HTCN) including a body portion having a first end and a second end, wherein the first end is opposed to the second end; and a head at the first end of the body portion, wherein the body portion has a predetermined curvilinear shape and includes a pointed tip at the second end of the body portion, and a method of surgically implanting universal horizontal-transvertebral curvilinear nail-screws (HTCN) into a plurality of adjacent vertebrae.

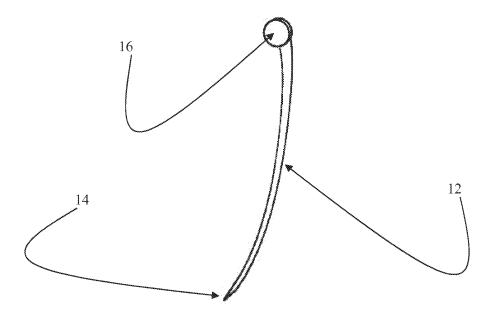
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<u>10</u>

FIGURE 1A

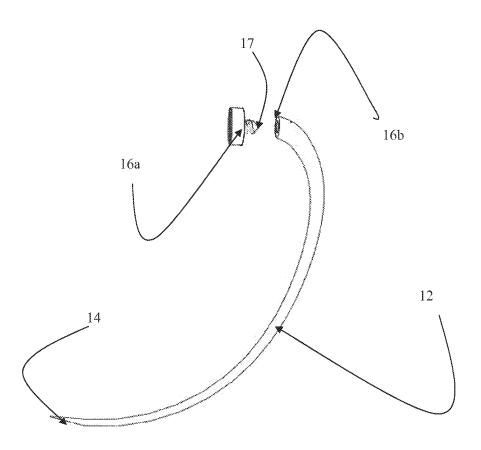
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<u>10</u>

FIGURE 1B

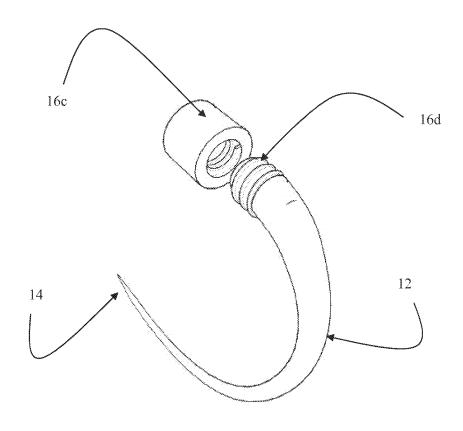
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<u>10</u>

FIGURE 1C

4



<u>10</u>

FIGURE 1D

5

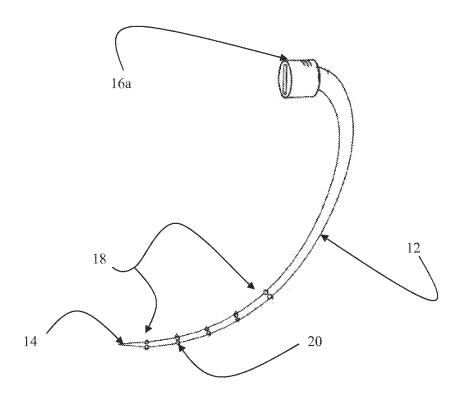


FIGURE 1E

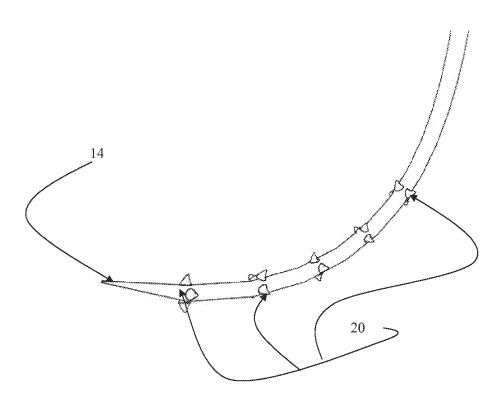


FIGURE 1F

7

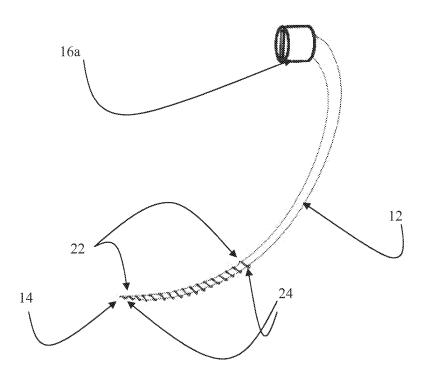


FIGURE 1G

8

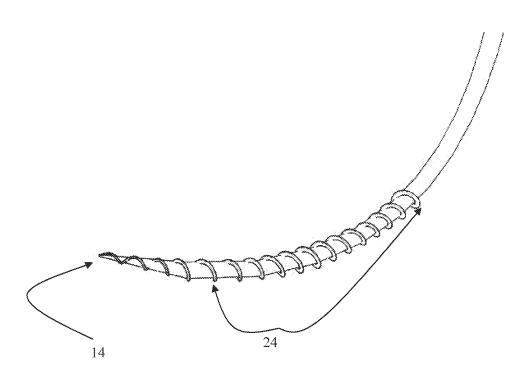


FIGURE 1H

9

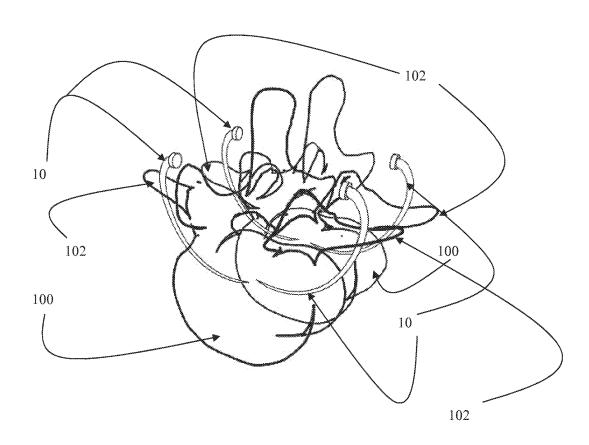


FIGURE 2A

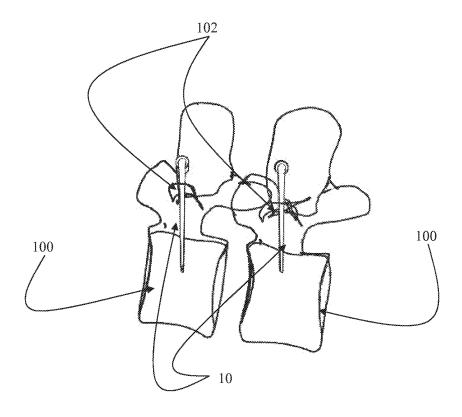


FIGURE 2B

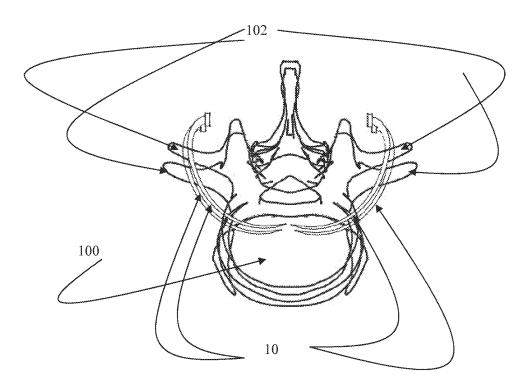


FIGURE 2C

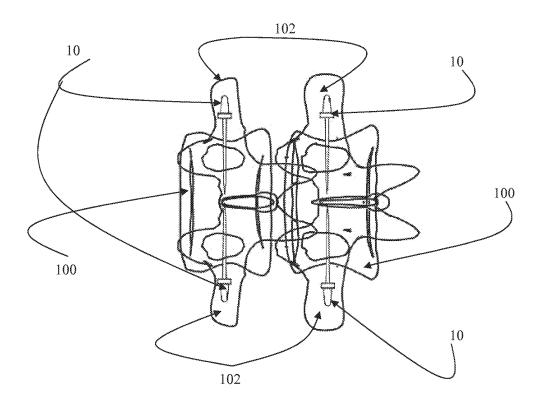


FIGURE 2D

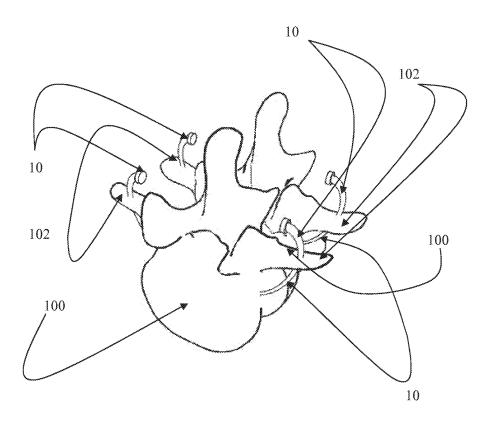


FIGURE 3A

14

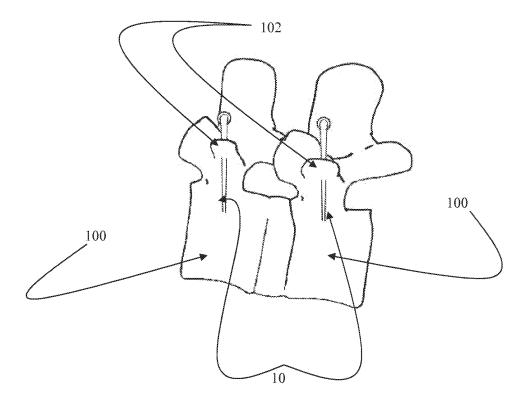


FIGURE 3B

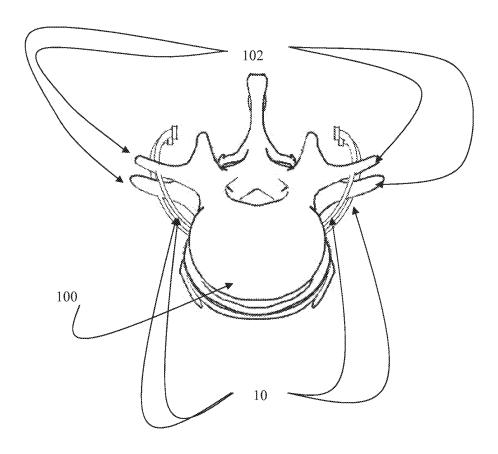


FIGURE 3C

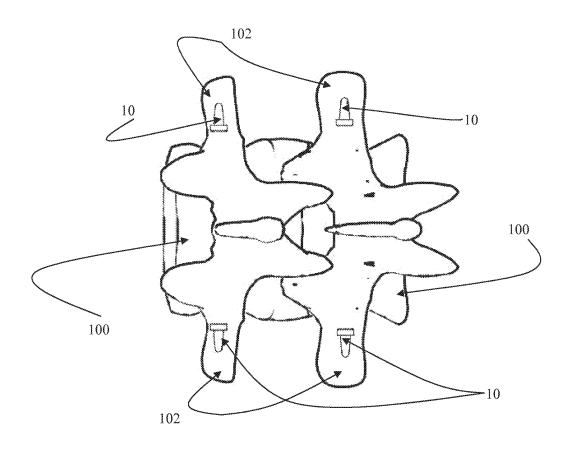


FIGURE 3D

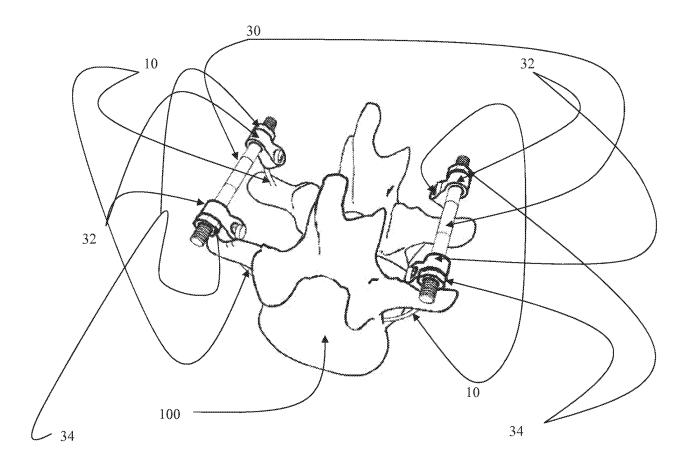


FIGURE 4A

18

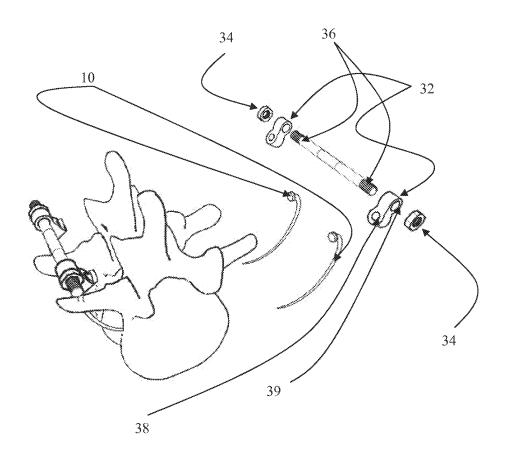


FIGURE 4B

19

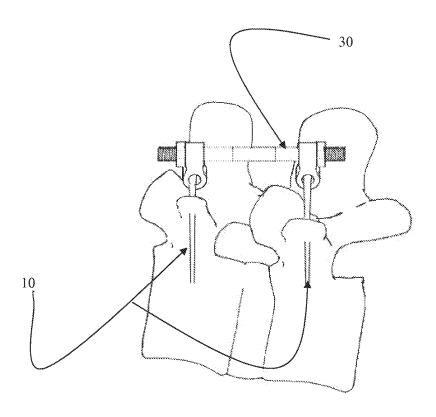


FIGURE 4C

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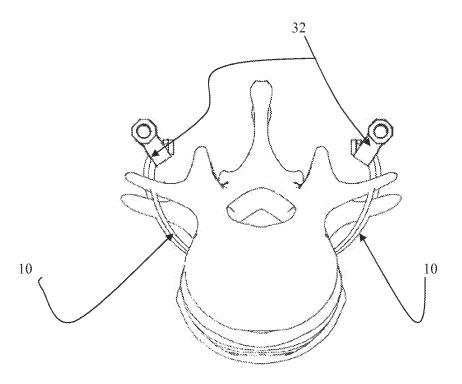


FIGURE 4D

21

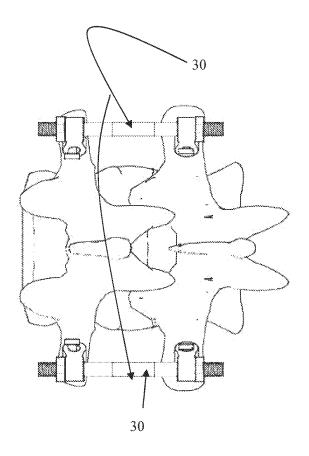


FIGURE 4E

22

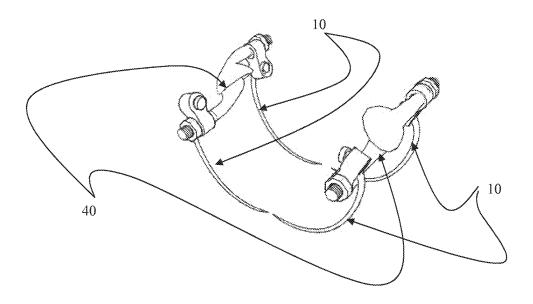


FIGURE 5A

23

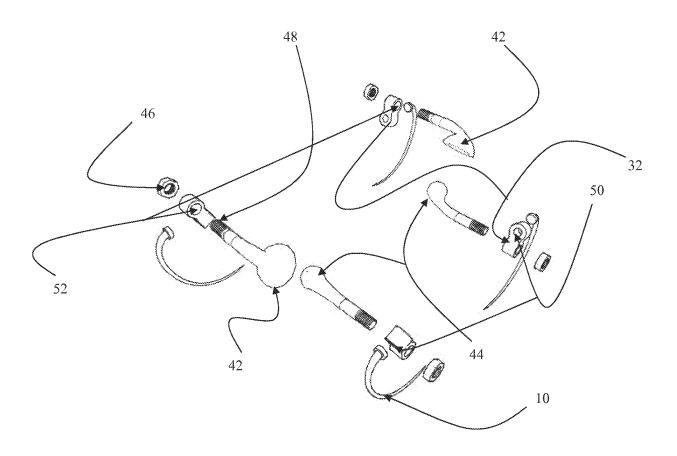


FIGURE 5B

24

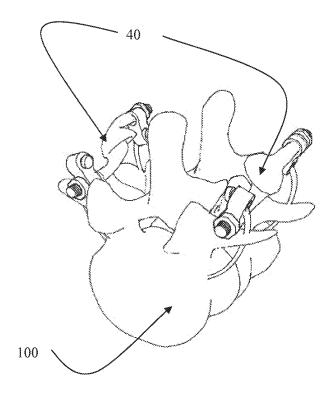


FIGURE 6A

25

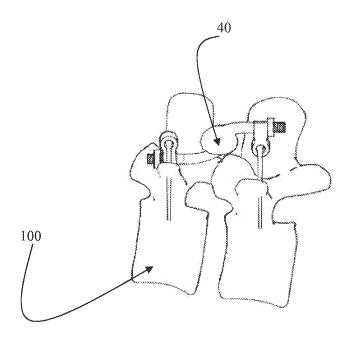


FIGURE 6B

26

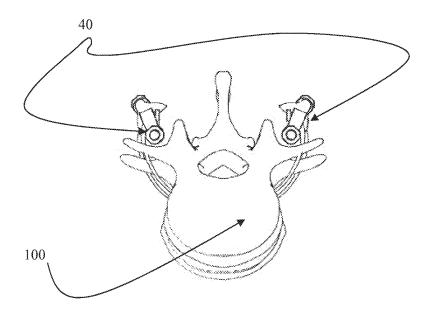


FIGURE 6C

27

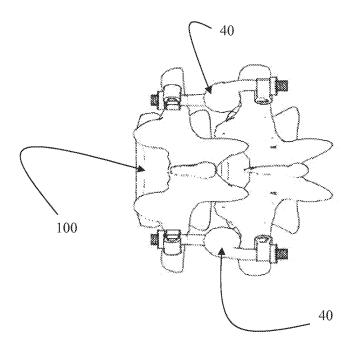


FIGURE 6D

28

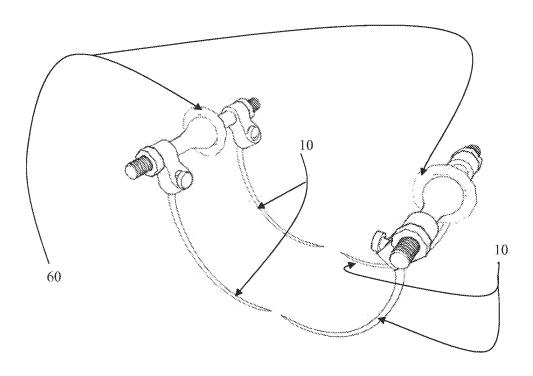


FIGURE 7A

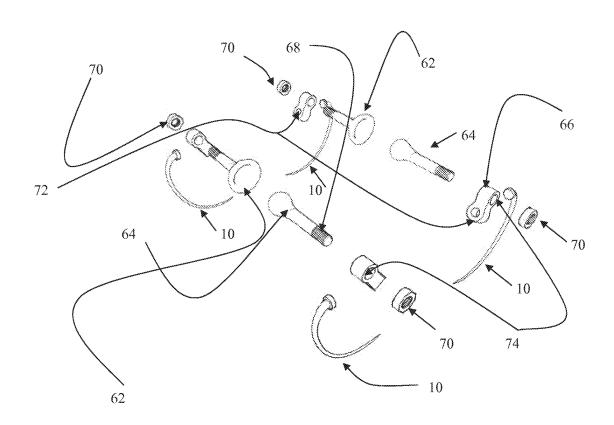


FIGURE 7B

30

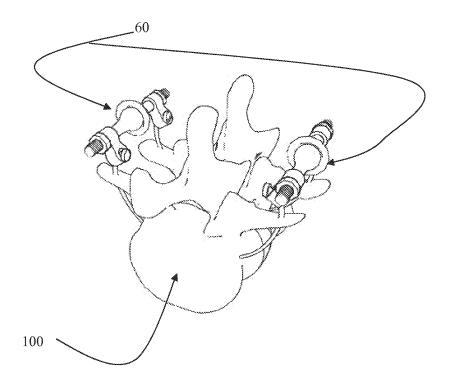


FIGURE 8A

31

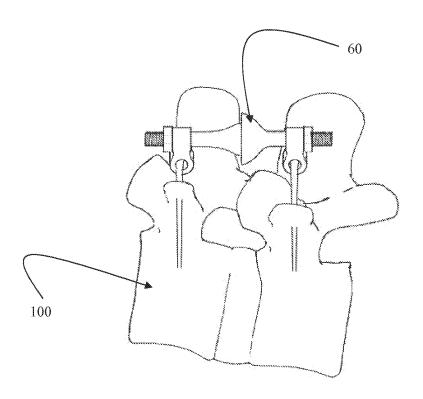


FIGURE 8B

32

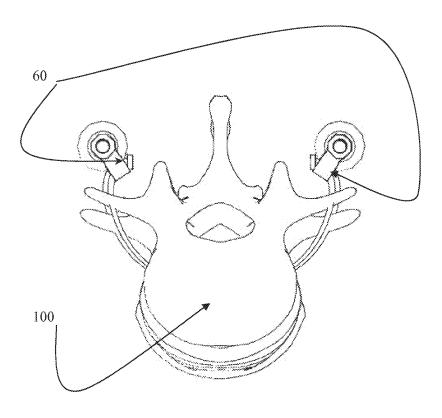


FIGURE 8C

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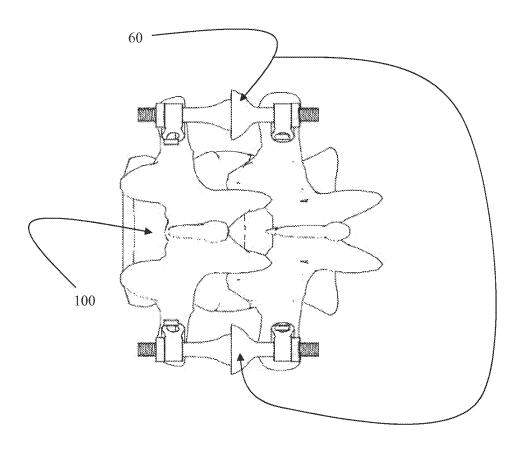


FIGURE 8D

## POWER OF ATTORNEY BY APPLICANT

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K2	(Note: The boxes above may be left blank if information is provided on the Transmittal.)						
	I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter, which may be an application filed after the date of this power of attorney, or identified above:						
	OR	:	26191				
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	Inventor or Joint Inventor (title not required below)						
	Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)						
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The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).							
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Name Title		Nathan C. Moskowitz	X	,			
NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.							
<u> </u>	Total of	forms are submitted.			.,		

61531511.doc

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Application Number	To Be Assigned					
Filing Date	Herewith					
First Named Inventor	Nathan C. Moskowitz					
Title	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION					
Art Unit	Unknown					
Examiner Name	Unknown					
Attorney Docket Number	45335-0013002					
SIGNATURE of Applicant or Patent Practitioner						
Signature /Stuart A. Nel	son/	Date (Optional)	1/4/2018			
Name Stuart A. No	elson	Registration Number	63,947			
Title (if Applicant is a juristic entity)						
Applicant Name (if Applicant is a jurist	c entity)					
NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.  *Total of forms are submitted.						

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Electronic Patent Application Fee Transmittal					
Application Number:					
Filing Date:	***************************************				
Title of Invention:	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER- LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION				
First Named Inventor/Applicant Name:	Nat	han C. Moskowitz			
Filer:	Stu	art A. Nelson/Abby	Remer		
Attorney Docket Number:	453	335-0013002			
Filed as Small Entity					
Filing Fees for Track   Prioritized Examination - Nonpr	ovis	ional Applicatio	n under 35 l	JSC 111(a)	
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:					
UTILITY FILING FEE (ELECTRONIC FILING)		4011	1	70	70
UTILITY SEARCH FEE		2111	1	300	300
UTILITY EXAMINATION FEE		2311	1	360	360
REQUEST FOR PRIORITIZED EXAMINATION		2817	1	2000	2000
Pages:					
Claims:					
Miscellaneous-Filing:					
PROCESSING FEE, EXCEPT PROV. APPLS.		2830	1	70	70

# Case 2:20-cv-03271-MSG Document 324-3 Filed 11/29/23 Page 74 of 194

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
	Tot	al in USD	(\$)	2800

Electronic Acknowledgement Receipt				
EFS ID:	31405489			
Application Number:	15862016			
International Application Number:				
Confirmation Number:	6203			
Title of Invention:	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER- LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION			
First Named Inventor/Applicant Name:	Nathan C. Moskowitz			
Customer Number:	26191			
Filer:	Stuart A. Nelson/Paul Stovenour			
Filer Authorized By:	Stuart A. Nelson			
Attorney Docket Number:	45335-0013002			
Receipt Date:	04-JAN-2018			
Filing Date:				
Time Stamp:	14:15:07			
Application Type:	Utility under 35 USC 111(a)			

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Payment was successfully received in RAM	\$2800
RAM confirmation Number	010518INTEFSW00000449061050
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	Track1.pdf	150359 eb0360304421dad4f2b97cb2fd8f8982b67 6282a	no	2
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Information:					
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2	Transmittal of New Application	PapTrans.pdf	61b2f1111e7978d48403776afb8a102d811 bd7e3	no	3
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	Document Des	scription	Start	E	nd
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	Claims 22		Ž	22	
	Abstract		23	23	
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5	Drawings-only black and white line drawings	Figures.pdf	1092684 	no	33

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### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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Doc Code: TRACK1.REQ

**Document Description: TrackOne Request** 

PTO/AIA/424 (03-14)

C	CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)				
First Named Inventor:	Nathan C. Moskowitz	Non provisional Application Number (if known):			
Title of Invention:	HORIZONTAL-TRANSVERTEBRAL RIGID OR JOINTED FLEXIBLE ROD		H INTER-LOCKING		

# APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

- 1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
- 2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims.
- 3. The applicable box is checked below:
- i. (a) The application is an original non provisional utility application filed under 35 U.S.C. 111(a).
   This certification and request is being filed with the utility application via EFS-Web.
  - (b) The application is an original non provisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filled with the application.
  - II. Request for Continued Examination Prioritized Examination under § 1.102(e)(2)
- i. A request for continued examination has been filed with, or prior to, this form.
- ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
- iii. The application is an original non provisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Stuart A. Nelson/	Date 1/4/2018
Name (Print/Typed) Stuart A. Nelson	Practitioner Registration Number 63,947
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for Submit multiple forms if more than one signature is required.*	signature requirements and certifications.
*Total of forms are submitted.	

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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Nathan C. Moskowitz Art Unit: Unknown Serial No.: 15/862,016 Examiner: Unknown

Filed : January 4, 2018

Title : HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-

SCREWS WITH INTER-LOCKING RIGID OR JOINTED

FLEXIBLE RODS FOR SPINAL FUSION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## **PRELIMINARY AMENDMENT**

Prior to examination, please amend the application as indicated on the following pages.

Serial No. 15/862.016 Filed January 4, 2018

Page 2 of 8

## Amendments to the Specification:

Please replace the paragraph beginning after the title with the following amended paragraph:

This application is a Continuation of Application Serial No. 12/957,776 filed December 1, 2010, which is a Continuation-In-Part of Application Serial No. 12/471,340 filed on May 22, 2009, now U.S. Patent No. 8,734,516 issued May 27, 2014, which is a Continuation-In-Part of Application Serial No. 12/054,335 filed on March 24, 2008, now U.S. Patent No. 7,972,363 issued July 5, 2011, which is a Continuation-In-Part of Application Serial No. 11/842,855 filed August 21, 2007, now U.S. Patent No. 7,942,903 issued May 17, 2011, which is a Continuation-In-Part of Application Serial No. 11/536,815 filed September 29, 2006, now U.S. Patent Application No. 7,846,188 issued December 7, 2010, and 12/957,776 filed December 1, 2010, claims priority under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 60/670,231, filed on April 12, 2005, and U.S. Provisional Application No. 61/265,752, filed on December 1, 2009; the entire contents of all the above identified patent applications are hereby incorporated by reference in their entirely.

 Serial No.
 : 15/862,016

 Filed
 : January 4, 2018

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 : 3 of 8

## Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

## Listing of Claims:

- 1. (Cancelled)
- 2. (New) A spinal fusion implant comprising:
  - a first curvilinear nail-screw for penetration and implantation into a first vertebral body along a first curved trajectory that avoids penetrating pedicles, wherein the first curvilinear nail screw extends from a first proximal end to a first distal end along the first curved trajectory with a first head at the first proximal end and a first bone penetrating pointed tip at the first distal end, wherein the first curvilinear nail-screw comprises first means for engaging a first cancellous core of the first vertebral body positioned along a first distal portion of the first curvilinear nailscrew proximate the first distal end;
  - a second curvilinear nail-screw for penetration and implantation into a second vertebral body along a second curved trajectory that avoids penetrating pedicles, wherein the second curvilinear nail screw extends from a second proximal end to a second distal end along the second curved trajectory with a second head at the second proximal end and a second bone penetrating pointed tip at the second distal end, wherein the second curvilinear nail-screw comprises second means for engaging a second cancellous core of the second vertebral body positioned along a second distal portion of the second curvilinear nail-screw proximate the second distal end; and
  - a connecting support structure defining a first hole sized and configured for receiving the first curvilinear nail screw and a second hole sized and configured for receiving the second curvilinear nail screw such that the first curvilinear nail-

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> screw is held with respect to the second curvilinear nail-screw with the first curvilinear nail-screw extending into the first vertebral body without penetrating pedicles and the second curvilinear nail-screw extending into the second vertebral body without penetrating pedicles.

- 3. (New) The spinal fusion implant of claim 2, and further comprising first and second rotatable connectors configured for retaining the first and second curvilinear nail-screws to the connecting support structure.
- 4. (New) The spinal fusion implant of claim 2, wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body comprise radially arranged fish-hooks.
- 5. (New) The spinal fusion implant of claim 2, wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body comprise threads.
- 6. (New) The spinal fusion implant of claim 2, wherein the first curvilinear nail-screw comprises a first smooth portion between the first head and the first distal portion and wherein the second curvilinear nail-screw comprises a second smooth portion between the second head and the second distal portion, and wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body each comprise one or more ridges.
- 7. (New) The spinal fusion implant of claim 2, wherein the connecting support comprises at least first and second components, wherein the first component defines the first hole for the first curvilinear nail screw, and wherein the first component is connected directly to the second component.

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; 5 of 8

8. (New) The spinal fusion implant of claim 7, wherein the connecting support comprise a third component that defines the second hole for the second curvilinear nail screw and wherein the third component is connected directly to the second component.

- 9. (New) The spinal fusion implant of claim 2, wherein the connecting support structure is a bar.
- 10. (New) The spinal fusion implant of claim 2, wherein the first and second curvilinear nailscrews are oriented by the connecting support structure to be introduced laterally into the first and second vertebral bodies.
- 11. (New) The spinal fusion implant of claim 2, wherein the first and second curvilinear nailscrews are oriented by the connecting support structure to be introduced posteriorly into the first and second vertebral bodies.
- 12. (New) The spinal fusion implant of claim 2, wherein the first and second curvilinear nailscrews are oriented by the connecting support structure to be introduced anteriorly into the first and second vertebral bodies.
- 13. (New) The spinal fusion implant of claim 2, wherein the first and second heads comprise first and second caps.
- 14. (New) The spinal fusion implant of claim 2, wherein the connecting support structure is sized and configured to be positioned exterior to the first and second vertebral bodies when connecting the first and second curvilinear nail-screws while the first and second curvilinear nail-screws penetrate into the first and second vertebral bodies.
- 15. (New) A method of implanting a spinal fusion implant, the method comprising: implanting a first curvilinear nail-screw to penetrate into a first vertebral body along a first curved trajectory that avoids pedicles, wherein the first curvilinear nail screw extends from a first proximal end to a first distal end along the first curved

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> trajectory with a first head at the first proximal end and a first bone penetrating pointed tip at the first distal end, wherein the first curvilinear nail-screw comprises first means for engaging a first cancellous core of the first vertebral body positioned along a first distal portion of the first curvilinear nail-screw proximate the first distal end, wherein the first head is positioned exterior to the first vertebral body and the first distal portion is positioned in the first cancellous core when implanted;

implanting a second curvilinear nail-screw to penetrate into a second vertebral body along a second curved trajectory that avoids pedicles, wherein the second curvilinear nail screw extends from a second proximal end to a second distal end along the second curved trajectory with a second head at the second proximal end and a second bone penetrating pointed tip at the second distal end, wherein the second curvilinear nail-screw comprises second means for engaging a second cancellous core of the second vertebral body positioned along a second distal portion of the second curvilinear nail-screw proximate the second distal end, wherein the second head is positioned exterior to the second vertebral body and the second distal portion is positioned in the second cancellous core when implanted;

connecting the first curvilinear nail-screw to the second curvilinear nail-screw via a connecting support structure such that the first curvilinear nail-screw is held with respect to the second curvilinear nail-screw with the first curvilinear nail-screw extending into the first vertebral body without penetrating pedicles and the second curvilinear nail-screw extending into the second vertebral body without penetrating pedicles.

16. (New) The method of claim 15, wherein the first curvilinear nail-screw penetrates into the first vertebral body so as to traverse no more than 50% of the first vertebral body and the second curvilinear nail-screw penetrates into the second vertebral body so as to traverse no more than 50% of the second vertebral body.

First Named Inventor : Nathan C. Moskowitz
Serial No. : 15/862,016
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17. (New) The method of claim 15, wherein the first and second curvilinear nail-screws penetrate into the first and second vertebral bodies without traversing an intervertebral disk.

- 18. (New) The method of claim 15, wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body comprise radially arranged fish-hooks.
- 19. (New) The method of claim 15, wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body comprise threads.
- 20. (New) The method of claim 15, wherein the first and second curvilinear nail-screws are introduced laterally into the first and second vertebral bodies.
- 21. (New) The method of claim 15, wherein the first and second curvilinear nail-screws are introduced anteriorly into the first and second vertebral bodies.

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 Filed
 : January 4, 2018

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## REMARKS

With this amendment, claim 1 is cancelled without prejudice and claims 2-21 are added. Support for this amendment can be found throughout the specification and claims. Applicant asks that all claims be examined in view of the amendment to the claims.

No fees are believed to be due. Please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

/Stuart A. Nelson/ Date: <u>1/8/2018</u>

> Stuart A. Nelson Reg. No. 63,947

Customer Number 26191 Fish & Richardson P.C. Telephone: (612) 337-2538

Facsimile: (877) 769-7945

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Electronic Acknowledgement Receipt				
EFS ID:	31433116			
Application Number:	15862016			
International Application Number:				
Confirmation Number:	6203			
Title of Invention:	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER- LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION			
First Named Inventor/Applicant Name:	Nathan C. Moskowitz			
Customer Number:	26191			
Filer:	Stuart A. Nelson/Abby Remer			
Filer Authorized By:	Stuart A. Nelson			
Attorney Docket Number:	45335-0013002			
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Application Type:	Utility under 35 USC 111(a)			

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### New Applications Under 35 U.S.C. 111

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### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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Title of Invention		L-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR EXIBLE RODS FOR SPINAL FUSION
As the belo	w named invent	or, I hereby declare that:
This declar is directed t		The attached application, or
A 100 11 10 10 10 10 10 10 10 10 10 10 10	[X]	United States application or PCT international application number 15/862,016
		filed on Sanuary 4, 2018.
The above-	denlified applica	tilon was made or authorized to be made by me.
I believe tha	it I am the origin	al inventor or an original joint inventor of a claimed invention in the application.
Petitioner/a contribute to cother than to support a petitioners/o USPTO, Pe application paient, Funt referenced	pplicant is caution to the pplicant is caution in the pplicant is caution or an applicante shoul distinct applicante phormore, the recipient applicante in a published a	warning:  warning:  warning:  med to avoid submitting personal information in documents filed in a patent application that may be resonal information such as social security numbers, bank account numbers, or credit card numbers to card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO polication, if this type of personal information is included in documents submitted to the USPTO documents submitted to the USPTO, documents redacting such personal information from the documents before submitting them to the tis advised that the record of a patent application is available to the public after publication of the ublication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a condition or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms yment purposes are not retained in the application file and therefore are not publicfy available.
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This declaration [ ] The ettached application, or is directed to:						
		[X]	United States application or PCT international application number	15/862,018		
			filed on January 4, 2018.			
The above-i	dentifiec	i applicai	tion was made or authorized to be made by me.			
I believe the	t lam th	ne origina	at inventor or an original joint inventor of a claimed invention in	the application.		
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LEGAL NAME OF INVENTOR  Inventor: Mosheh T. Moskowitz Oate (Optional): 1 5 1 0  Signature:						
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Title of Invention	3				CURVILINEAR NA NAL FUSION	IL-SCREWS V	WITH INTER-LOCKING RIGID OR
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			filed on	January 4, 20	18.	garoussussussussussussussussussussussussuss	
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contribute to (other than to support a petitioners/s USPTO, Pe application patent. Furt referenced	o identi a checi i pelilio ipplica fitioner (uniess hermor in a pul	iy theft. Pi k or credit n or an ap nts should /applicant a non-pu 's, the rec bliehed ap	ersonal inforcerd authorophication. If toonsider retained in advised to the conference ord from an aphication or conference ord from an aphication or conference.	mation such a rization form P1 this type of per reacting such p that the record juest in complic abandoned ap an issued pate	s social security nur FO-2036 submitted to recent information is rersonal information of a patent application ance with 37 CFR 1, relication may also to int (see 37 CFR 1,14	nbers, bank acc or payment purp included in doc from the docum on is available to 213(a) is made e available to tif 4). Checks and r	d in a patent application that may lount numbers, or credit card numbers poses) is never required by the USPTO luments submitted to the USPTO, lents before submitting them to the lothe public after publication of the in the application) or issuance of a le public if the application is credit card authorization forms efore are not publicly available.
LEGAL NAME OF INVENTOR							
inventor	<u>Ah</u>	iminon Q.	Moskovit	<u> </u>		Date (Option	93) de la companya del companya de la companya del companya de la
Signature			777774	no produce		Land of the second	
					toluding naming the en A/01 form for each add		ly, must accompany this form

This collection of information is required by 35 U.S.C. 118 and 37 OFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 36 U.S.C. 122 and 37 CFR 1.11 and 1.14. This objection is estimated to take 1 minute to complete, including gethering, preparing, and submitting the completed application from the HSPTO. Time will vary depending upon the individual case. Any comments on this amount of time you require to complete this form and/or suggestions for reducing trus burden, should be sent to the Chief Information Officer, U.S. Paters and Trademark Office, U.S. Department of Commence, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1458, Alexandria, VA 22313-1450.

If you need a scienarie in completing the form, call 1-800-PTO-9199 and select option 2.

61013339.doc

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Nathan C. Moskowitz Art Unit Unknown Serial No. : 15/862.016 Examiner : Unknown Filed : January 4, 2018 Conf. No. : 6203

Title : HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-

SCREWS WITH INTER-LOCKING RIGID OR JOINTED

FLEXIBLE RODS FOR SPINAL FUSION

### MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT

Please consider the references listed on the enclosed PTO-1449 Form.

Under 35 USC §120, this application relies on the earlier filing date of application serial number 12/957,776, filed on December 1, 2010. All references listed on the PTO-1449 Form were submitted to and/or cited by the Office in the prior application, and so copies of those references are not provided in this application.

This statement is being filed within three months of the filing date of the application or before the receipt of a first action on the merits.

Apply any necessary charges or credits to deposit account 06-1050, referencing the above attorney docket number.

Please contact the undersigned if there are any questions regarding this statement.

Respectfully submitted,

Date:	1/10/2018	/Stuart A. Nelson/	
		Stuart A. Nelson	
		Reg. No. 63,947	

Customer Number 26191 Fish & Richardson P.C. Telephone: (612) 337-2538 Facsimile: (877) 769-7945

61617735.doc

# Case 2:20-cv-03271-MSG Document 324-3 Filed 11/29/23 Page 94 of 194

Attorney Docket: 45335-0013002

First Named Inventor : Nathan C. Moskowitz
Serial No. : 15/862,016
Filed : January 4, 2018
Page : 2 of 2

Sheet <u>1</u> of <u>4</u>

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 45335-0013002	Application No. 15/862,016	
Information Disclosu by Applica		Applicant Nathan C. Moskowitz		
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date January 4, 2018	Group Art Unit	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	8,105,362	01-2012	Duarte			
	2.	2008/0045951	02-2008	Fanger et al.			
	3.	5,609,593	03-1997	Errico et al.			
	4.	7,713,289	05-2010	Matthys			
	5.	7,879,036	02-2011	Biedermann et al.			
	6.	6,652,527	11-2003	Zucherman et al.			
	7.	4,274,401	06-1981	Miskew			
	8.	2010/0094346	04-2010	Matityahu			
	9.	4,790,303	12-1988	Steffee			
	10.	2,430,293	11-1947	Howells			
	11.	8,357,198	01-2013	McGraw et al.			
	12.	6,689,125	02-2004	Keith et al.			
	13.	5123926	1992-06-23	Pisharodi			
	14.	5514180	1996-05-07	Heggeness et al.			
	15.	6368350	2002-04-09	Erickson et al.			
	16.	6419704	2002-07-16	Ferree			
	17.	6458159	2002-10-01	Thalgott			
	18.	6527804	2003-03-04	Gauchet et al.			
	19.	6533818	2003-03-18	Weber et al.			
	20.	6579318	2003-06-17	Varga et al.			
	21.	6582468	2003-06-24	Gauchet			
	22.	6719794	2004-04-13	Gerber			
	23.	6733532	2004-05-11C	Gauchet et al.			
	24.	6764491	2004-07-20	Frey et al.			
	25.	6770094	2004-08-03	Fehling et al.			
	26.	6572653	2003-06-03	Simonson			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if n	ot in conformance and not considered. Include copy of this form with

next communication to applicant.

Substitute Disclosure Form

Sheet <u>2</u> of <u>4</u>

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 45335-0013002	Application No. 15/862,016	
Information Disci		Applicant Nathan C. Moskowitz		
(Use several sheets if necessary)  37 CFR §1.98(b))		Filing Date January 4, 2018	Group Art Unit	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	27.	5782832	1998-07-21	Larsen et al.			
	28.	6641614	2003-11-04	Wagner et al.			
	29.	6126689	2000-10-03	Brett			
	30.	6375682	2002-04-23	Fleischmann et al.			
	31.	6723126	2004-04-20	Berry			
	32.	5667472	1997-09-07	Finn et al.			
	33.	6955671	2005-10-18	Uchikubo			
	34.	7037258	2006-05-02	Chatenever et al.			
	35.	6904308	2005-06-07	Frisch et al.			
	36.	7097615	2006-08-29	Banik et al.			
	37.	7030904	2006-04-18	Adair et al.			
***************************************	38.	4997432	1991-03-05	Keller			
	39.	5960522	1999-10-05	Boe			
	40.	5660188	1997-08-26	Groiso			
	41.	4960420	1990-10-02	Goble et al.			
	42.	4636217	1987-01-13	Ogilvie et al.			
	43.	4554914	1985-11-26	Kapp et al.			
	44.	6953477	2005-10-11	BERRY			
	45.	4599086	1986-07-08	DOTY			
	46.	5062850	1991-11-05	MACMILLAN et al.			
	47.	5290312	1994-03-01	KOJIMOTO et al.			
	48.	5865848	1999-02-02	Baker			
	49.	7211112	2007-05-01	Baynham et al.			
	50.	5405391	1995-04-11	Henderson et al.			
	51.	7862616	2011-01-04	Lechmann et al.			
	52.	6972019	2005-12-06	Michelson			

Examiner Signature	Date Considered
	L
EXAMINER: Initials citation considered. Draw line through citation if no	ot in conformance and not considered. Include copy of this form with
next communication to applicant.	

Substitute Disclosure Form

Sheet <u>3</u> of <u>4</u>

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 45335-0013002	Application No. 15/862,016	
Information Disclos by Applic		Applicant Nathan C. Moskowitz		
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date January 4, 2018	Group Art Unit	

	U.S. Patent Documents						
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	53.	6629998	2003-10-07	Lin			
	54.	6824564	2004-11-30	Crozet			
	55.	7442209	2008-10-28	Michelson			
	56.	6342074	2002-01-29	Simpson			
	57.	6558423	2003-05-06	Michelson			
	58.	6432106	2002-08-13	Fraser			
	59.	7326248	2008-02-05	Michelson			
***************************************	60.	7033394	2006-04-25	Michelson			
	61.	5888223	1999-03-30	Bray, Jr.			
	62.	8403986	2013-03-26	Michelson			
	63.	8328872	2012-12-11	Duffield et al.			
	64.	20040088054	2004-05-06	Berry			
	65.	20050273170	2005-12-08	Navarro et al.			
	66.	20040177531	2004-09-16	DiBenedetto et al.			
	67.	20050278026	2005-12-15	Gordon, et al.			
	68.	20050216084	2005-09-29	Fleischmann			
	69.	20050027362	2005-02-03	Williams et al.			
	70.	20050049590	2005-03-03	Alleyne et al.			
	71.	20040254644	2004-12-16	Taylor			
	72.	20020143338	2002-10-03	ORBAYet al.			
	73.	20050177235	2005-08-11	BAYNHAM et al.			
	74.	20020068977	2002-06-06	JACKSON			
	75.	20070213820	2007-09-13	MAGERL etal			
	76.	20100145460	2010-06-10	McDonough et al.			
	77.	20090105831	2009-04-23	Jones et al.			
	78.	8951295	2/2015	Matityahu et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if no	ot in conformance and not considered. Include copy of this form with
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Substitute Disclosure Form

Sheet <u>4</u> of <u>4</u>

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office		Application No. 15/862,016	
Information Disclo		Applicant Nathan C. Moskowitz		
(Use several sheets if necessary) (37 CFR \$1.98(b))		Filing Date January 4, 2018	Group Art Unit	

U.S. Patent Documents									
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate		
	79.	20010021852	9/2001	Chappius					
	80.	20080188896	8/2008	Sevrain					
	81.	6471707	10/2002	Miller et al.					
	82.	6558386	5/2003	Cragg					
	83.	20100211108	8/2010	Lemole					
	84.	4013207	3/1977	ErkenBrack					
	85.	4165597	8/1979	Scanland et al					

Foreign Patent Documents or Published Foreign Patent Applications									
Examiner	Desig.	Document	Publication	Country or			Trans	lation	
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No	
	86.	2004093749	2004-11-04	WO					
	87.	2006091503	2006-08-31	wo					

(	Other Documents (include Author, Title, Date, and Place of Publication)						
Examiner	Desig.						
Initial	ID	Document					
	88.	Vincent C. TRAYNELIS, "Prosthetics and Biologics: The Wave of the Future," CLINICAL NEUROSURGERY, Volume 50, Proceedings of the Congress of Neurological Surgeons, Philadelphia, PA 2002, Chapter 9, pages 207-219					
		E.K. WAI et al "Disk Replacement Arthroplasties: Can The Success of Hip and Knee Replacements be Repeated in the Spine?." Seminars in Spine Surgery, Vol. 15, No. 4 (December) 2003, pp 473-482					
	90.	Richard D. GUYER et al., "Intervertebral Disc Prostheses," SPINE JOURNAL, Volume 28, Number 15S, Supp. To 8/1/03, pages S15-S23					
	91.	DIETER GROB et al., "Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine," SPINE, Vol. 30, No. 3, 2005, pp. 324-331					
	92.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 03 December 2007, International Application No. PCT/US 07/05005					
	93.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 21 May 2008, International Application No. PCT/US2007/021015					
	94.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 09 July 2008, International Application No. PCT/US2007021013					

Examiner Signature	Date Considered
·	
EXAMINER: Initials citation considered. Draw line through citation if n	ot in conformance and not considered. Include copy of this form with
next communication to applicant	

Electronic Acknowledgement Receipt					
EFS ID:	31457632				
Application Number:	15862016				
International Application Number:					
Confirmation Number:	6203				
Title of Invention:	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER- LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION				
First Named Inventor/Applicant Name:	Nathan C. Moskowitz				
Customer Number:	26191				
Filer:	Stuart A. Nelson/Melissa Andersen				
Filer Authorized By:	Stuart A. Nelson				
Attorney Docket Number:	45335-0013002				
Receipt Date:	10-JAN-2018				
Filing Date:					
Time Stamp:	12:11:44				
Application Type:	Utility under 35 USC 111(a)				

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File Listing:							
Document Number	Document Description		File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)	
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### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS Post 1450 Alexandria, Virginia 22313-1450 www.uspio.gov

FILING or GRPART FIL FEE REC'D TOT CLAIMS IND CLAIMS NUMBER 371(c) DATE UNIT ATTY.DOCKET.NO 15/862,016 01/04/2018 3733 730 45335-0013002 20

26191 FISH & RICHARDSON P.C. (TC) PO BOX 1022 MINNEAPOLIS, MN 55440-1022

**CONFIRMATION NO. 6203 FILING RECEIPT** 

Date Mailed: 01/30/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections

Inventor(s)

Nathan C. Moskowitz, Rockville, MD; Mosheh T. Moskowitz, Rockville, MD; Ahmnon D. Moskowitz, Rockville, MD;

Applicant(s)

Nathan C. Moskowitz, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 26191

Domestic Priority data as claimed by applicant

This application is a CON of 12/957,776 12/01/2010 PAT 9888918 which is a CIP of 12/471,340 05/22/2009 PAT 8734516 which is a CIP of 12/054,335 03/24/2008 PAT 7972363 which is a CIP of 11/842,855 08/21/2007 PAT 7942903 which is a CIP of 11/536,815 09/29/2006 PAT 7846188 which is a CIP of 11/208,644 08/23/2005 PAT 7704279 and said 12/957,776 12/01/2010 claims benefit of 60/670,231 04/12/2005

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see <a href="http://www.uspto.gov">http://www.uspto.gov</a> for more information.) - None. Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

and claims benefit of 61/265,752 12/01/2009

page 1 of 4

### Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 01/26/2018

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/862,016** 

Projected Publication Date: 05/10/2018

Non-Publication Request: No Early Publication Request: No

\*\* SMALL ENTITY \*\*

Title

HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION

**Preliminary Class** 

606

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

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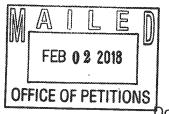
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	FOR NUMBER FILED NUMBER EXTRA		RAT	E(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
	BASIC FEE (37 CFR 1.18(a), (b), or (c))		N	/A	75		N/A				
	RCH FEE FR 1.16(k), (i), or (m))	N	/A	١	J/A	N	/A	330	1	N/A	
EXA	MINATION FEE FR 1.16(o), (p), or (q))	N	/A	١	I/A	N	/A	380		N/A	
TOT	AL CLAIMS FR 1.16(i))	20	minus	20=		× 5	i0 =	0.00	OR		***************************************
INDE	PENDENT CLAIMS	S 2	minus	3 = *		× 2	30 =	0.00		***************************************	
APF FEE	PLICATION SIZE	sheets of p \$310 (\$155 50 sheets	paper, th 5 for sm or fraction	and drawings e e application si all entity) for ea on thereof. See ' CFR 1.16(s).	ze fee due is ch additional	-		0.00	<b>q</b>		
MUL	TIPLE DEPENDEN	IT CLAIM PRE	SENT (3	7 CFR 1.16(j))				0.00	1		
* If th	ne difference in colu	ımn 1 is less th	an zero,	enter "0" in colur	mn 2.	TO	ΓAL.	785		TOTAL	
NTA		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RA	E(\$)	ADDITIONAL FEE(\$)	<b>decrees</b>	RATE(\$)	ADDITIONAL FEE(\$)
WEN THE	Total * (37 CFR 1.16(i))	- AMENDMENT	Minus	**	=	  x	=	***************************************	OR	χ =	
AMENDMENT	Independent * (37 OFR 1.16(h))		Minus	* 4 *	=	X			OR	х =	
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	FIRST PRESENTAT	ION OF MULTIPL	E DEPEN	DENT CLAIM (37 (	DFR 1.16(j))				OR		
							TAL L FEE		OR	TOTAL ADD'L FEE	
e F		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RA <sup>-</sup>	~E(\$)	ADDITIONAL FEE(\$)	<b>P</b>	RATE(\$)	ADDITIONAL FEE(\$)
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ENDMENT	Independent * (37 CFR 1.16(h))		Minus	***	=	×	2:		OR	х =	
AM	Application Size Fee (37 CFR 1.16(s))							]			
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
						ADD'	TAL L FEE		OR	TOTAL ADD'L FEE	
*:	* If the entry in colu * If the "Highest Nu * If the "Highest Num The "Highest Numbe	mber Previous ber Previously I	ly Paid F Paid For"	or" IN THIS SPA IN THIS SPACE I	CE is less than s less than 3, eni	20, enter " ter "3".		in column 1.	000000000000000000000000000000000000000	***************************************	***************************************



## UNITED STATES PATENT AND TRADEMARK OFFICE

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Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

Doc Code: TRACK1.GRANT

	Prior	n Granting Request for itized Examination ck I or After RCE)	Application No.: 15/862,016				
1.	THE R	EQUEST FILEDJanuary 4, 2	018 IS <b>GRANTED</b> .				
	The above-identified application has met the requirements for prioritized examination  A.						
2.			ndergo prioritized examination. The application will be course of prosecution until one of the following occurs:				
	A.	filing a <b>petition for extension of</b>	f time to extend the time period for filing a reply;				
	В.	filing an amendment to amend	the application to contain more than four independent				
		claims, more than thirty total c	laims, or a multiple dependent claim;				
	C.	filing a request for continued ex	xamination;				
	D.	filing a notice of appeal;					
	E.	filing a request for suspension of	action;				
	F.	mailing of a notice of allowance;					
	G.	mailing of a final Office action;					
	H.	completion of examination as de-	fined in 37 CFR 41.102; or				
	I.	abandonment of the application.					
	Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.						
	/Brian W. [Signate		Petitions Examiner, Office of Petitions (Title)				

U.S. Patent and Trademark Office PTO-2298 (Rev. 02-2012)



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/862,016	01/04/2018	Nathan C. Moskowitz	45335-0013002	6203
	7590 02/21/2018 ARDSON P.C. (TC)		EXAM	INER
PO BOX 1022	, ,		JOHANAS, JA	CQUELINE T
MINNEAPOL	IS, MN 55440-1022		ART UNIT	PAPER NUMBER
			3733	***************************************
			NOTIFICATION DATE	DELIVERY MODE
			02/21/2018	ELECTRONIC

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

	Application No.	Applicant(s)				
Examiner-Initiated Interview Summary	15/862,016	MOSKOWITZ ET	ſ AL.			
Examiner-initiated interview Julimiary	Examiner	Art Unit				
	Jacqueline Johanas	3733				
All participants (applicant, applicant's representative, PTO	personnel):					
(1) Jacqueline Johanas.	(3)					
(2) Stuart Nelson (Reg. 63947).	(4)					
Date of Interview: 12 February 2018.						
Type:  Telephonic  Video Conference  Personal [copy given to:  applicant [	applicant's representative]					
Exhibit shown or demonstration conducted: Yes If Yes, brief description:	☑ No.					
Issues Discussed 101 112 102 103 Other (For each of the checked box(es) above, please describe below the issue and details						
Claim(s) discussed: <u>2-21</u> .						
Identification of prior art discussed: <u>n/a</u> .						
Substance of Interview (For each issue discussed, provide a detailed description and indicate if agreement reference or a portion thereof, claim interpretation, proposed amendments, arguments.)		entification or clarifica	tion of a			
Examiner called to request oral election between apparatus apparatus claims without traverse.	claims (2-14) and method clai	ms (15-21). Appl	licant elected			
Applicant recordation instructions: It is not necessary for applicant to p	ovide a separate record of the substar	nce of interview.				
<b>Examiner recordation instructions</b> : Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.						
Attachment						
/Jacqueline Johanas/ Primary Examiner, Art Unit 3733						

U.S. Patent and Trademark Office PTOL-413B (Rev. 8/11/2010)

Interview Summary

	Application No. 15/862,016	Applicant(s) MOSKOWIT		
Office Action Summary	Examiner Jacqueline Johanas	Art Unit 3733	AIA (First Inventor to File) Status No	
The MAILING DATE of this communication app	l pears on the cover sheet with the c	L corresponden	j	
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filled after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1) Responsive to communication(s) filed on 01/08  A declaration(s)/affidavit(s) under 37 CFR 1.1				
· —	action is non-final.			
<ul> <li>3) An election was made by the applicant in responsible.</li> <li>12 February 2018; the restriction requirement at the since this application is in condition for alloware closed in accordance with the practice under Exercise.</li> </ul>	and election have been incorporance except for formal matters, pro	ated into this assecution as	action. to the merits is	
Disposition of Claims*				
5)  Claim(s) 2-21 is/are pending in the application. 5a) Of the above claim(s) 15-21 is/are withdrawn from consideration.  6)  Claim(s) is/are allowed.  7)  Claim(s) 2-14 is/are rejected.  8)  Claim(s) is/are objected to.  9)  Claim(s) are subject to restriction and/or election requirement.  * If any claims have been determined allowable, you may be eligible to benefit from the Patent Prosecution Highway program at a participating intellectual property office for the corresponding application. For more information, please see <a href="http://www.uspto.gov/patents/init_events/pph/index.jsp">http://www.uspto.gov/patents/init_events/pph/index.jsp</a> or send an inquiry to PPHfeedback@uspto.gov.  Application Papers  10) The specification is objected to by the Examiner.				
11) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  Certified copies:  a) All b) Some** c) None of the:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  ** See the attached detailed Office action for a list of the certified copies not received.				
Attachment(s)	_			
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SPaper No(s)/Mail Date 01/10/2018.</li> </ol>	3) ⊠ Interview Summary Paper No(s)/Mail D  5B/08b) 4) □ Other:			

U.S. Patent and Trademark Office PTOL-326 (Rev. 11-13)

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The present application is being examined under the pre-AIA first to invent

provisions.

**DETAILED ACTION** 

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-14, drawn to a spinal fusion implant, classified in A61B17/7001.

II. Claims 15-21, drawn to a method of implanting a spinal fusion implant,

classified in A61B17/88.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be practiced with another materially different product such as an implant comprising a connecting support structure having a solid rod (i.e. a structure absent any holes) which is seated within a head of the first and second curvilinear nail-screws.

Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

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the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries); the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

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During a telephone conversation with Stuart Nelson (reg. 63947) on 02/12/2018 a provisional election was made without traverse to prosecute the invention of Group I, claims 2-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the

issues. See MPEP § 804.01.

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rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. Failure to do so may result in no rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent

### **Priority**

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, 365(c), or 386(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent

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application and in the later-filed application must be sufficient to comply with the requirements of 35 U.S.C. 112(a) or the first paragraph of pre-AIA 35 U.S.C. 112, except for the best mode requirement. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994)

The disclosure of the prior-filed applications, Application No. 12/471,340, 12/054,335, 11/842,855, 11/536,815, and 60/670,231, fail to provide adequate support or enablement in the manner provided by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph for one or more claims of this application. Support for the subject matter of claims 2-14 is only found in the disclosures of prior-filed application no. 12/957,776 and 61/265,752. Accordingly, the effective filing date for claims 2-14 of the current application is 12/01/2009.

### Specification

Amendment to the specification filed 01/08/2018 has been entered.

The disclosure is objected to because of the following informalities:

[0002], "NTCN's" should be "HTCN's"

[0040], "HTCN 100" should be "HTCN 10"

[0041], "HTCNs 100" should be "HTCNs 10"

[0046], "THCNs" should be "HTCNs"

[0055], "THCNs" should be "HTCNs"

Appropriate correction is required.

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### Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. — An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Claim limitations "first means for engaging a first cancellous core of the first vertebral body" and "second means for engaging a second cancellous core of the second vertebral body" has/have been interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because it uses/they use a generic placeholder "first/second means" coupled with functional language "for engaging a first/second cancellous core of the first/second vertebral body" without reciting sufficient structure to achieve the function. Furthermore, the generic placeholder is not preceded by a structural modifier.

Since the claim limitation(s) invokes 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, claim(s) 2-3, 7-14 has/have been interpreted to cover the corresponding structure described in the specification that achieves the claimed function, and equivalents thereof.

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A review of the specification shows that the following appears to be the corresponding structure described in the specification for the 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph limitation:

[0034] Figures 1E and F illustrate an exemplary embodiment of an HTCN 10 including a fish-hooked tail or portion 18 (embodiment IV). In this embodiment, the tail 18 of the HTCN 10 can include a series of radially arranged fish-hooks 20 to engage the cancellous core of the vertebral body. Figure I F is an enlargement illustrating details of an exemplary embodiment of the radial fish-hook 18.

[0035] Figures 1 G and H illustrate an exemplary embodiment of an HTCN 10 including a threaded tail-screw 22 (embodiment V). The threaded tail 22 can include **threads 24 that can engage the cancellous core of the vertebral body**. Figure 1H is an enlargement illustrating details of an exemplary embodiment the threads 24.

If applicant wishes to provide further explanation or dispute the examiner's interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

If applicant does not intend to have the claim limitation(s) treated under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may amend the claim(s) so that it/they will clearly not invoke 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites/recite sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

For more information, see MPEP § 2173 et seq. and Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 FR 7162, 7167 (Feb. 9, 2011).

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## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim(s) **2, 5-14** is/are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Matityahu et al. (US Publication No. 2010/0016903 A1) (from hereon referred to as Matityahu).

RE. Claim 2, Matityahu discloses a spinal fusion implant (Fig. 10) comprising:

a first curvilinear nail-screw (30) which is fully capable of penetration and implantation into a first vertebral body along a first curved trajectory which is fully capable of avoiding pedicles, wherein the first curvilinear nail screw extends from a first proximal end to a first distal end along the first curved trajectory with a first head at the first proximal end and a first bone penetrating pointed tip at the first distal end (see figure below), wherein the first curvilinear nail-screw comprises first means for engaging a first cancellous core of the first vertebral body positioned along a first distal portion of the first curvilinear nail- screw proximate the first distal end (as described in [0043 and 0048], outer surface 78 of the shaft of the anterior portion 86 may be threaded such that it permits screwing of the anterior portion into the vertebral body or may include a

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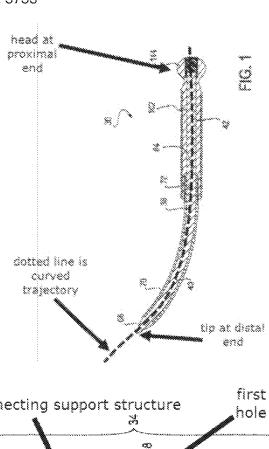
roughened surface along at least a portion thereof, further head 68 which is proximate the distal end is disclosed as threaded 82 in [0044]);

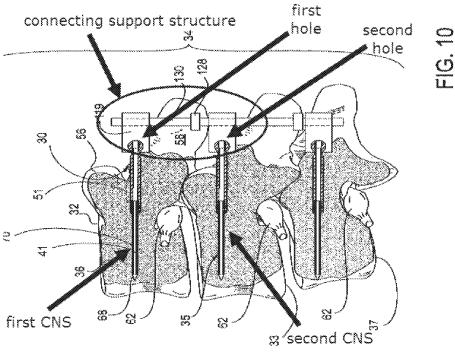
a second curvilinear nail-screw (30) which is fully capable of penetration and implantation into a second vertebral body along a second curved trajectory that is fully capable of avoiding penetrating pedicles, wherein the second curvilinear nail screw extends from a second proximal end to a second distal end along the second curved trajectory with a second head at the second proximal end and a second bone penetrating pointed tip at the second distal end (see figure below), wherein the second curvilinear nail-screw comprises second means for engaging a second cancellous core of the second vertebral body positioned along a second distal portion of the second curvilinear nail-screw proximate the second distal end (as described in [0043 and 0048], outer surface 78 of the shaft of the anterior portion 86 may be threaded such that it permits screwing of the anterior portion into the vertebral body or may include a roughened surface along at least a portion thereof, further head 68 which is proximate the distal end is disclosed as threaded 82 in [0044]); and

a connecting support structure defining a first hole sized and configured for receiving the first curvilinear nail screw and a second hole sized and configured for receiving the second curvilinear nail screw such that the first curvilinear nail- screw is fully capable of being held with respect to the second curvilinear nail-screw with the first curvilinear nail-screw fully capable of extending into the first vertebral body without penetrating pedicles and the second curvilinear nail-screw fully capable of extending into the second vertebral body without penetrating pedicles.

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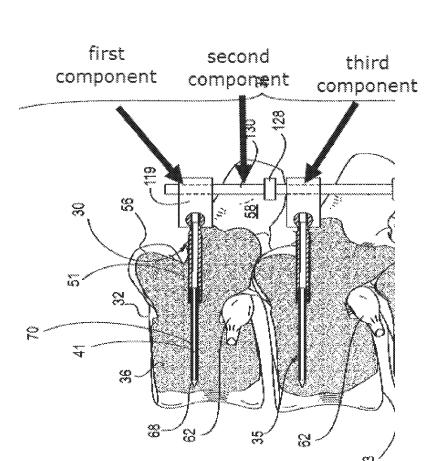
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RE. Claim 5, the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body comprise threads [0043, 0044, 0048].

Re. Claim 6, the first curvilinear nail-screw comprises a first smooth portion between the first head and the first distal portion and wherein the second curvilinear nail-screw comprises a second smooth portion between the second head and the second distal portion (CNS are disclosed as having a smooth outer surface 84 at the posterior portion 66 which is in between the anterior portion 86 or portion 68 and the head 114, further neck 116 is located between 68/86 and 114 and is smooth), and wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body each comprise one or more ridges (threads of 68 and 86 are considered ridges).

Re. claim 7-8, the connecting support comprises at least first and second components, wherein the first component defines the first hole for the first curvilinear nail screw, and wherein the first component is connected directly to the second component, wherein the connecting support comprise a third component that defines the second hole for the second curvilinear nail screw and wherein the third component is connected directly to the second component (See figure below).

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Re claim 9, the connecting support structure is a bar (element 130 can be considered a bar as described in [0068]).

Re. claims 10-12, the first and second curvilinear nail- screws are oriented by the connecting support structure to be fully capable of being introduced anteriorly, laterally or posteriorly into the first and second vertebral bodies (first and second CNSs are fully

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capable of being introduced in any direction, including posteriorly, laterally and

anteriorly).

Re. claim 13, the first and second heads (114) comprise first and second caps

(elements 102 can be considered caps).

Re. Claim 14, the connecting support structure fully capable of being positioned

exterior to the first and second vertebral bodies when connecting the first and second

curvilinear nail-screws while the first and second curvilinear nail-screws penetrate into

the first and second vertebral bodies (shown in Fig. 10).

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35

U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any

correction of the statutory basis for the rejection will not be considered a new ground of

rejection if the prior art relied upon, and the rationale supporting the rejection, would be

the same under either status.

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis

for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the

time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was

made.

Claims 2-3, 7-14 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being

unpatentable over Lieberman (US Publication No. 2003/0181913 A1).

Re. Claim 2, Lieberman discloses a spinal fusion implant (Fig. 11) comprising:

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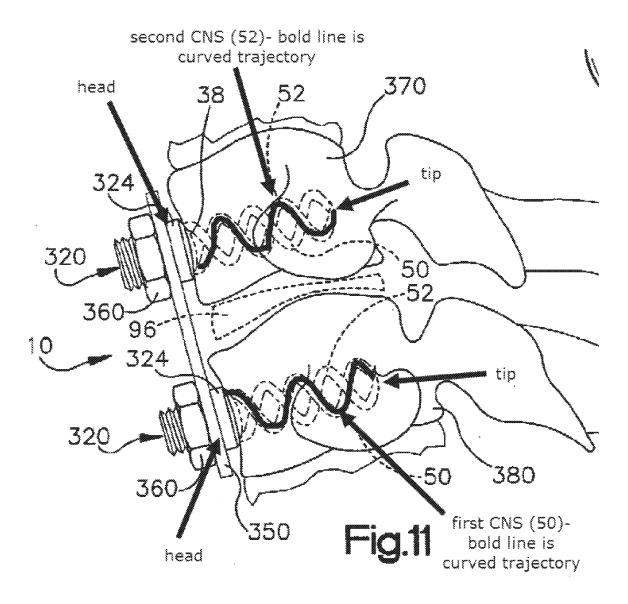
a first curvilinear nail-screw (50, see figure below) for penetration and implantation into a first vertebral body along a first curved trajectory (curved trajectory is path of helical tunnel as described in [0047]) that avoids penetrating pedicles (shown in Fig. 11 implanted anteriorly, avoiding pedicles), wherein the first curvilinear nail screw extends from a first proximal end to a first distal end along the first curved trajectory with a first head (320) at the first proximal end and a first bone penetrating pointed tip at the first distal end (see figure below),

a second curvilinear nail-screw (52, see figure below) for penetration and implantation into a second vertebral body along a second curved trajectory (curved trajectory is path of helical tunnel as described in [0047]) that avoids penetrating pedicles (Fig. 11), wherein the second curvilinear nail screw extends from a second proximal end to a second distal end along the second curved trajectory with a second head (320) at the second proximal end and a second bone penetrating pointed tip at the second distal end (see figure below); and

a connecting support structure (350) defining a first hole (352) sized and configured for receiving the first curvilinear nail screw (Fig. 10-11) and a second hole (354) sized and configured for receiving the second curvilinear nail screw (Fig. 10-11) such that the first curvilinear nail- screw is held with respect to the second curvilinear nail-screw with the first curvilinear nail-screw extending into the first vertebral body without penetrating pedicles and the second curvilinear nail-screw extending into the second vertebral body without penetrating pedicles (configuration shown in Fig. 11).

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Lieberman discloses that the curvilinear nail-screws contain an outer surface which engages the cancellous core of the vertebral bodies in which they are positioned [0047] (shown in Fig. 11), however Lieberman is silent to structure such as fish hooks, threads or equivalents thereof on the curvilinear nail-screws. Lieberman discloses

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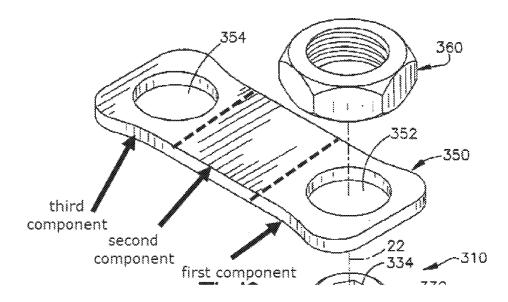
surface treatment on the outer surface of the implant which includes a porous texture, formed by mesh, beads, or a coating such as a ceramic coating that increases the surface area of the end surface to promote bone in-growth and thus help with long term fixation of the anchor to the bone [0034]. It would have been obvious to one having ordinary skill in the art at the time the time the invention was made to modify the outer surface of the curvilinear nail screws to include a porous texture as taught by Lieberman in order to promote bone ingrowth into the distal portion of the implant and thus help with long term fixation of the anchor within the bone. The porous texture is considered by the Office to be a means for engaging a cancellous core of a vertebral body.

Re. Claim 3, further comprising first and second rotatable connectors (360, 360) configured for retaining the first and second curvilinear nail-screws to the connecting support structure (Fig. 10-11) [0059].

Re. Claim 7-8, the connecting support comprises at least first and second components, wherein the first component defines the first hole for the first curvilinear nail screw, and wherein the first component is connected directly to the second component and the connecting support comprise a third component that defines the second hole for the second curvilinear nail screw and wherein the third component is connected directly to the second component (see figure below).

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Re. Claim 9, the connecting support structure is a bar (shape of 350 shown in Fig. 10 can be considered a bar).

Re. Claim 10, the first and second curvilinear nail- screws are oriented by the connecting support structure to be fully capable of being introduced laterally into the first and second vertebral bodies (first and second CNSs can be introduced in any direction, for example a lateral trajectory is shown in Fig. 3).

Re. Claim 11, the first and second curvilinear nail- screws are oriented by the connecting support structure to be fully capable of being introduced posteriorly into the first and second vertebral bodies (first and second CNSs are fully capable of being introduced in any direction, including posteriorly).

Re. Claim 12, the first and second curvilinear nail- screws are oriented by the connecting support structure to be introduced anteriorly into the first and second

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vertebral bodies (first and second CNSs can be introduced in any direction, for example

an anterior trajectory is shown in Fig. 11).

Re. Claim 13, the first and second heads (320, 320) comprise first and second

caps (element 330 can be considered a cap or element 360 can be considered a cap,

Fig. 10).

Re. Claim 14, the connecting support structure (350) is sized and configured to

be positioned exterior to the first and second vertebral bodies when connecting the first

and second curvilinear nail-screws while the first and second curvilinear nail-screws (50,

52) penetrate into the first and second vertebral bodies (shown in Fig. 11).

Claim 3 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable

over Matityahu in view of Fanger et al. (US Publication No. 2008/0045951 A1) (from

hereon referred to as Fanger).

Matityahu discloses the implant as described in the rejection of claim 2 above.

Matityahu discloses that tulip assemblies are used to connect the heads of the CNS to

the cross link bar/rod of the connecting support structure [0068]. However, Matityahu is

silent to rotatable connectors configured for retaining the first and second curvilinear

nail-screws to the connecting support structure.

Fanger discloses a spinal fusion implant in the same field of endeavor which

uses locking screws/set screws (70) to tighten a connecting support structure (26) to a

tulip (40) and compress the tulip and support structure against the screw head (56)

thereby securing the entire screw/tulip/rod assembly together [0062] (Fig. 5). It would

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have been obvious to one having ordinary skill in the art at the time the invention was made to use a set screw (a rotatable connector) to secure the screws with the tulip and connecting support structure as taught by Fanger in order to easily tighten all components with a single tool using a single action thereby locking the orientation of the device relative to the patient.

Claim 4 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Matityahu in view of McGraw et al. (US Publication No. 2008/0033432 A1) (from hereon referred to as McGraw).

Matityahu discloses the implant as described in the rejection of claim 2 above.

Matityahu discloses that either or both of the outer surface 78 of the shaft of the anterior portion 86 and the outer surface of 68 may have a roughened surface, however Matityahu is silent to said surfaces comprising radially arranged fish hooks.

McGraw discloses a spinal fusion implant in the same field of endeavor which comprises means for securing the device within the vertebrae which includes barbs or radially arranged fish hooks 32 proximate the distal end 26 of the implant (Fig. 4-5) [0054] for the purpose of stabilizing the implant within the bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use barbs or radially arranged fish hooks as taught by McGraw to create the roughened surface described by Matityahu in order to use a means for engaging the bone of the vertebrae known in the art to secure the sections of the implant within the vertebrae thereby preventing movement and loosening of the implant within the body.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See Form PTO-892

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Johanas whose telephone number is (571)270-5085. The examiner can normally be reached on Monday to Friday, 9:00am to 5:00pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline Johanas/ Primary Examiner, Art Unit 3733

	Application No.	Applicant(s)		
Examiner-Initiated Interview Summary	15/862,016	MOSKOWITZ ET AL.		
Examiner-induced interview Summary	Examiner	Art Unit		
	Jacqueline Johanas	3733		
All participants (applicant, applicant's representative, PTO p	ersonnel):			
(1) Jacqueline Johanas.	(3)			
(2) Stuart Nelson (Reg. 63947).	(4)			
Date of Interview: 12 February 2018.				
Type:  Telephonic  Video Conference  Personal [copy given to:  applicant	] applicant's representative]			
Exhibit shown or demonstration conducted: Yes If Yes, brief description:	] No.			
Issues Discussed 101 112 102 103 Other (For each of the checked box(es) above, please describe below the issue and detailed				
Claim(s) discussed: 2-21.				
Identification of prior art discussed: <u>n/a</u> .				
Substance of Interview (For each issue discussed, provide a detailed description and indicate if agreement were ference or a portion thereof, claim interpretation, proposed amendments, arguments.		entification or clarification of a		
Examiner called to request oral election between apparatus apparatus claims without traverse.	claims (2-14) and method clai	ms (15-21). Applicant elected		
Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.				
<b>Examiner recordation instructions</b> : Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.				
Attachment				
/Jacqueline Johanas/ Primary Examiner, Art Unit 3733				
U.S. Patent and Trademark Office PTOL-413B (Rev. 8/11/2010) Interview	Summary	Paper No. 20180213		

#### Application/Control No. Applicant(s)/Patent Under Reexamination 15/862,016 MOSKOWITZ ET AL. Notice of References Cited Art Unit Examiner Page 1 of 1 Jacqueline Johanas 3733 U.S. PATENT DOCUMENTS

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	К	US-				
	L	US-				
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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)			
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\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office PTO-892 (Rev. 01-2001)

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Part of Paper No. 20180213

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	15862016	MOSKOWITZ ET AL.
	Examiner	Art Unit
	JACQUELINE JOHANAS	3733

CPC- SEARCHED		
Symbol	Date	Examiner
a61b17/7001-7046,7056,7053,8625,86	2/14/2018	JJ
a61b2017/8655	2/14/2018	JJ

CPC COMBINATION SETS - SEARC		
Symbol	Date	Examiner

	US CLASSIFICATION SEARCHE	Đ	
Class	Subclass	Date	Examiner

 $<sup>^{\</sup>star}$  See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

SEARCH NOTE	:S	
Search Notes	Date	Examiner
EAST, inventor searches	2/14/2018	JJ

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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Part of Paper No.: 20180213

## EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp	
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S5	647	a61b17/7053.cpc.	US- PGPUB; USPAT	OR	ON	2018/02/13 12:47
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S22	1	("20100016903").PN.	US- PGPUB; USPAT	OR	OFF	2018/02/14 13:40

### **EAST Search History (Interference)**

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Sheet <u>1</u> of <u>4</u>

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office		Application No. 15/862,016	
Information Disclos by Appli		Applicant Nathan C. Moskowitz		
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date January 4, 2018	Group Art Unit	

	·			nt Documents		·	·
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
maca	1.	8,105,362	01-2012	Duarte	0.033	Oubciass	,,,,pp,op,ace
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Examiner Signature /JACQUELINE T JOHANAS/	Date Considered 02/13/2018
EXAMINER: Initials citation considered. Draw line through citation if no	of in conformance and not considered. Include copy of this form with

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next communication to applicant.

Sheet <u>2</u> of <u>4</u>

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office		Application No. 15/862,016	
Information Disclo by Appli		Applicant Nathan C. Moskowitz		
(Use several sheets if necessary) (37 CFR \$1.98(b))		Filing Date January 4, 2018	Group Art Unit	

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Examiner Signature /JACQUELINE T JOHANAS/	Date Considered 02/13/2018			
EXAMINER: Initials citation considered. Draw line through citation if no	t in conformance and not considered. Include copy of this form with			
next communication to applicant				

Substitute Disclosure Form

Sheet <u>3</u> of <u>4</u>

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office		Application No. 15/862,016	
Information Discl by App		Applicant Nathan C. Moskowitz		
(Use several sheets if necessary)		Filing Date January 4, 2018	Group Art Unit	
(37 CFR §1.98(b))		January 4, 2018		

				nt Documents			
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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Examiner Signature /JACQUELINE T JOHANAS/	Date Considered 02/13/2018
EXAMINER: Initials citation considered. Draw line through citation if no next communication to applicant.	ot in conformance and not considered. Include copy of this form with

Substitute Disclosure Form

Sheet <u>4</u> of <u>4</u>

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 45335-0013002	Application No. 15/862,016	
Information Disclos by Applic		Applicant Nathan C. Moskowitz		
(Use several sheets if necessary) (37 CFR \$1.98(b))		Filing Date January 4, 2018	Group Art Unit	

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Examiner Initial	Desig. ID	Document Number	Publication Date			Subclass	Filing Date If Appropriate			
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Examiner	Desig.	Document	Publication	Country or			Trans	slation			
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No			
	86,	2004093749	2004-11-04	WO							
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Examiner	Desig.	· ·
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Examiner Signature /JACQUELINE T JOHANAS/	Date Considered 02/13/2018	
EXAMINER: Initials citation considered. Draw line through citation if no next communication to applicant.	ot in conformance and not considered. Include copy of this form with	

Substitute Disclosure Form

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	15862016	MOSKOWITZ ET AL.
	Examiner	Art Unit
	JACQUELINE JOHANAS	3733

1	Rejected	××	Cancelled	N	Non-Elected	Α	Appeal
****	Allowed		Restricted	3000	Interference	0	Objected

Claims	renumbered	in the same o	der as presented		□ СРА	☐ T.E	D. 🗌	R.1.47		
CLAIM		DATE								
Final	Original	02/14/2018							T	
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	10	✓								
	11	✓								
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	19	N								
	20	N								
	21	N	-							

Part of Paper No.: 20180213

# Bibliographic Data

35 USC 119 (a-d) conditions met:

Application No: 15862016

O Yes No Foreign Priority claimed:  $\square_{\mathrm{Yes}}$ No.

Verified and Acknowledged: /jacqueline johanas/

> Examiner's Signature Initials

HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED

Met After Allowance

FLEXIBLE RODS FOR SPINAL FUSION

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
01/04/2018	606	3733	45335-0013002
RULE			

### **APPLICANTS**

Title:

Nathan C. Moskowitz, Rockville, MD, UNITED STATES

#### **INVENTORS**

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Mosheh T. Moskowitz, Rockville, MD, UNITED STATES

Ahmnon D. Moskowitz, Rockville, MD, UNITED STATES

### CONTINUING DATA

This application is a CON of 12957776 12/01/2010 PAT 9888918

12957776 has PRO of 61265752 12/01/2009

12957776 is a CIP of 12471340 05/22/2009 PAT 8734516

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12957776 has PRO of 60670231 04/12/2005

### FOREIGN APPLICATIONS

### IF REQUIRED, FOREIGN LICENSE GRANTED\*\*

01/26/2018

### STATE OR COUNTRY

**UNITED STATES** 

### ADDRESS

FISH & RICHARDSON P.C. (TC)

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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS PO Box 1450 Alexandra, Virginia 22313-1450 www.uspto.gov

APPLICATION NUMBER 15/862,016

FILING OR 371(C) DATE 01/04/2018

FIRST NAMED APPLICANT
Nathan C. Moskowitz

ATTY. DOCKET NO./TITLE 45335-0013002

CONFIRMATION NO. 6203
PUBLICATION NOTICE

26191 FISH & RICHARDSON P.C. (TC) PO BOX 1022 MINNEAPOLIS, MN 55440-1022

Title:HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER-LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION

Publication No.US-2018-0125483-A1 Publication Date:05/10/2018

#### NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Attorney Docket No.: 46440-0013002

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Nathan C. Moskowitz Art Unit: 3733

Serial No. : 15/862,016 Examiner : Jacqueline T. Johanas

Filed : January 4, 2018 Conf. No. : 6203

Title : HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-

SCREWS WITH INTER-LOCKING RIGID OR JOINTED

FLEXIBLE RODS FOR SPINAL FUSION

# Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

### REPLY TO ACTION OF FEBRUARY 21, 2018

Please consider the following reply.

# Case 2:20-cv-03271-MSG Document 324-3 Filed 11/29/23 Page 147 of 194

Attorney Docket: 46440-0013002

First Named Inventor : Nathan C. Moskowitz
Serial No. : 15/862,016
Filed : January 4, 2018
Page : 2 of 13

# Amendments to the Title:

Please replace the Title with the following amended Title:

SPINAL FUSION IMPLAINT WITH CUNVILINEAR NAIL-SCREWS

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### Amendment to the Specification:

Please amend paragraphs 0002, 0040, 0041, 0046, and 0055 as follows:

[0002] The present invention relates to a unique universal horizontal-transvertebral curvilinear nail-screw (HTCN) and to a method of applying such an HTCN to the spine, whereby a series of NTCN's HTCN's, according to the exemplary embodiments, can be implanted into adjacent vertebrae can be inter-connected with either rigid or flexible jointed rods, fusing two or more adjacent vertebral bodies together thereby achieving either rigid or flexible fusion, respectively, and thus obviating the need for pedicle screw fixation in many but not all cases. The exemplary embodiments also can be used to salvage and/or extend pre-existing pedicle screw fusions.

[0040] Figures 3A-D exemplarily illustrate the placement of a total of four HTCNs 10 into two adjacent non-transparent vertebral bodies 100 in order to achieve fusion of these two adjacent bodies. A first HTCN 10 is inserted unilaterally into the right nontransparent vertebral body 100, a second HTCN 10 is inserted unilaterally into the left non-transparent vertebral body 100, a third HTCN [[100]] 10 is inserted into the adjacent right non-transparent vertebral body 100, and a fourth HTCN 10 is inserted into the adjacent left non-transparent vertebral body 100. In the exemplary embodiment illustrated in Figures 3A-D, two of the HTCNs 10 are lined up on the right, and two of the HTCNs 10 are lined up on the left. The path of the curvilinear HTCNs 10 begins posteriorly, and its trajectory is horizontal from its entry point into the mid lateral vertebral body 100 to its final destination which is the relative center of the vertebral body 100.

[0041] The HTCNs [[100]] 10 are illustrated as perforating the transverse processes 102. Figures 3A-D illustrate an example of an estimated trajectory and orientation for avoiding (e.g., necessary to avoid) exiting nerve roots. In other embodiments, the entry point of the HTCN 10 can be more medial, lateral, caudal, or rostral to the transverse process 102. The initial position of insertion may be via posterior, lateral, or anterior surgical approaches.

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First Named Inventor: Nathan C. Moskowitz Attorney Docket: 46440-0013002

Serial No. : 15/862,016 Filed : January 4, 2018 Sena. . . Filed

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[0046] The exemplary embodiment is illustrated with two HTCNs 10 per connecting bar 30. However, one or ordinary skill in the art will recognize that more than two [[THCNs]] HTCNs 10 can be coupled to each connecting bar 30. Furthermore, the threading on the connecting bar 30 is not limited to the illustrated embodiment and can extend along a portion or all of the length of the connecting bar 30. For example, in an alternative embodiment, three or more nuts 34 can be secured to the threaded connecting bar 30 to secure two or more connecting bar links 34 (e.g., three or four links 34, etc.) to the connecting bar 30, such that two or more HTCNs 10 (e.g., three or four HTCNs 10, etc.) can be coupled to the same connecting bar 30. The diameter of the connecting bar 30 is illustrated as being uniform along a length of the connecting bar 30. However, other embodiments are possible in which the diameter of the body of the connecting bar 30, the diameter of the threads, etc. can be different at different portions of the connecting bar 30. Other embodiments can include more than two connecting bar links 32, and more than two tightening nuts 34.

[0055] The exemplary embodiment is illustrated with two HTCNs 10 per connecting bar 40. However, in alternative embodiments, more than two [[THCNs]] HTCNs 10 can be coupled to each connecting bar 40. Furthermore, the threading 48 on the connecting bar 40 is not limited to the illustrated embodiment. For example, in an alternative embodiment, three or more nuts 34 can be secured to the threaded connecting bar 40 to secure two or more connecting bar links 34 (e.g., three or four links 34, etc.) to the connecting bar 40, such that two or more HTCNs 10 (e.g., three HTCNs 10) can be coupled to the same connecting bar 40. Other embodiments can include more than two connecting bar links 32, and more than two tightening nuts 34.

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# List of claims (replacing prior versions).

1. (Cancelled)

### 2. (Currently Amended) A spinal fusion implant comprising:

- a first curvilinear nail-screw for penetration and implantation into a first vertebral body along a first curved trajectory that avoids penetrating pedicles, wherein the first curvilinear nail screw extends from a first proximal end to a first distal end along the first curved trajectory with a first head at the first proximal end and a first bone penetrating pointed tip at the first distal end, wherein the first curvilinear nail-screw comprises first means for engaging a first cancellous core of the first vertebral body positioned along a first distal portion of the first curvilinear nailscrew proximate the first distal end, wherein the first curved trajectory is along a first single continuous arc;
- a second curvilinear nail-screw for penetration and implantation into a second vertebral body along a second curved trajectory that avoids penetrating pedicles, wherein the second curvilinear nail screw extends from a second proximal end to a second distal end along the second curved trajectory with a second head at the second proximal end and a second bone penetrating pointed tip at the second distal end, wherein the second curvilinear nail-screw comprises second means for engaging a second cancellous core of the second vertebral body positioned along a second distal portion of the second curvilinear nail-screw proximate the second distal end, wherein the second curved trajectory is along a second single continuous arc; and
- a connecting support structure defining a first hole sized and configured for receiving the first curvilinear nail screw and a second hole sized and configured for receiving the second curvilinear nail screw such that the first curvilinear nailscrew is held with respect to the second curvilinear nail-screw with the first

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curvilinear nail-screw extending into the first vertebral body without penetrating pedicles and the second curvilinear nail-screw extending into the second vertebral body without penetrating pedicles.

- 3. (Previously Presented) The spinal fusion implant of claim 2, and further comprising first and second rotatable connectors configured for retaining the first and second curvilinear nail-screws to the connecting support structure.
- 4. (Previously Presented) The spinal fusion implant of claim 2, wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body comprise radially arranged fish-hooks.
- 5. (Previously Presented) The spinal fusion implant of claim 2, wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body comprise threads.
- 6. (Previously Presented) The spinal fusion implant of claim 2, wherein the first curvilinear nail-screw comprises a first smooth portion between the first head and the first distal portion and wherein the second curvilinear nail-screw comprises a second smooth portion between the second head and the second distal portion, and wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body each comprise one or more ridges.
- 7. (Currently Amended) The spinal fusion implant of claim 2, wherein the connecting support comprises at least first and second separate components, wherein the first component defines the first hole for the first curvilinear nail screw, and wherein the first component is connected directly to the second component.

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8. (Previously Presented) The spinal fusion implant of claim 7, wherein the connecting support comprise a third component that defines the second hole for the second curvilinear nail screw and wherein the third component is connected directly to the second component.

- 9. (Previously Presented) The spinal fusion implant of claim 2, wherein the connecting support structure is a bar.
- 10. (Previously Presented) The spinal fusion implant of claim 2, wherein the first and second curvilinear nail-screws are oriented by the connecting support structure to be introduced laterally into the first and second vertebral bodies.
- 11. (Previously Presented) The spinal fusion implant of claim 2, wherein the first and second curvilinear nail-screws are oriented by the connecting support structure to be introduced posteriorly into the first and second vertebral bodies.
- 12. (Previously Presented) The spinal fusion implant of claim 2, wherein the first and second curvilinear nail-screws are oriented by the connecting support structure to be introduced anteriorly into the first and second vertebral bodies.
- 13. (Previously Presented) The spinal fusion implant of claim 2, wherein the first and second heads comprise first and second caps.
- 14. (Previously Presented) The spinal fusion implant of claim 2, wherein the connecting support structure is sized and configured to be positioned exterior to the first and second vertebral bodies when connecting the first and second curvilinear nail-screws while the first and second curvilinear nail-screws penetrate into the first and second vertebral bodies.
- 15. (Withdrawn, Currently Amended) A method of implanting a spinal fusion implant, the method comprising:

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> implanting a first curvilinear nail-screw to penetrate into a first vertebral body along a first curved trajectory that avoids pedicles, wherein the first curvilinear nail screw extends from a first proximal end to a first distal end along the first curved trajectory with a first head at the first proximal end and a first bone penetrating pointed tip at the first distal end, wherein the first curvilinear nail-screw comprises first means for engaging a first cancellous core of the first vertebral body positioned along a first distal portion of the first curvilinear nail-screw proximate the first distal end, wherein the first head is positioned exterior to the first vertebral body and the first distal portion is positioned in the first cancellous core when implanted, wherein the first curved trajectory is along a first single continuous arc;

> implanting a second curvilinear nail-screw to penetrate into a second vertebral body along a second curved trajectory that avoids pedicles, wherein the second curvilinear nail screw extends from a second proximal end to a second distal end along the second curved trajectory with a second head at the second proximal end and a second bone penetrating pointed tip at the second distal end, wherein the second curvilinear nail-screw comprises second means for engaging a second cancellous core of the second vertebral body positioned along a second distal portion of the second curvilinear nail-screw proximate the second distal end, wherein the second head is positioned exterior to the second vertebral body and the second distal portion is positioned in the second cancellous core when implanted, wherein the second curved trajectory is along a second single continuous arc;

> connecting the first curvilinear nail-screw to the second curvilinear nail-screw via a connecting support structure such that the first curvilinear nail-screw is held with respect to the second curvilinear nail-screw with the first curvilinear nail-screw extending into the first vertebral body without penetrating pedicles and the second curvilinear nail-screw extending into the second vertebral body without penetrating pedicles.

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16. (Withdrawn) The method of claim 15, wherein the first curvilinear nail-screw penetrates into the first vertebral body so as to traverse no more than 50% of the first vertebral body and the second curvilinear nail-screw penetrates into the second vertebral body so as to traverse no more than 50% of the second vertebral body.

- 17. (Withdrawn) The method of claim 15, wherein the first and second curvilinear nail-screws penetrate into the first and second vertebral bodies without traversing an intervertebral disk.
- 18. (Withdrawn) The method of claim 15, wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body comprise radially arranged fish-hooks.
- 19. (Withdrawn) The method of claim 15, wherein the first means for engaging a first cancellous core of the first vertebral body and the second means for engaging a second cancellous core of the second vertebral body comprise threads.
- 20. (Withdrawn) The method of claim 15, wherein the first and second curvilinear nail-screws are introduced laterally into the first and second vertebral bodies.
- 21. (Withdrawn) The method of claim 15, wherein the first and second curvilinear nail-screws are introduced anteriorly into the first and second vertebral bodies.
- 22. (New) The spinal fusion implant of claim 2, wherein the first curvilinear nail-screw shares a first centerline axis with the first hole where the first curvilinear nail-screw extends through the first hole and wherein the second curvilinear nail-screw shares a second centerline axis with the second hole where the second curvilinear nail-screw extends through the second hole.

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23. (New) The spinal fusion implant of claim 2, wherein the first and second curvilinear nail-screws connect to the first and second holes of the support structure at curved portions of the first and second curvilinear nail-screws.

24. (New) The spinal fusion implant of claim 2, wherein the first curvilinear nail-screw is curved from the first proximal end to the first distal end including a portion of the first curvilinear nail-screw connected to the connecting support structure and the second curvilinear nail-screw is curved from the second proximal end to the second distal end including a portion of the second curvilinear nail-screw connected to the connecting support structure.

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#### <u>REMARKS</u>

With this amendment, claims 2, 7, and 15 are amended without prejudice and claims 22-24 are added.

#### Examiner Interview

On May 15, 2018 an Examiner Interview was conducted between Examiner Jacqueline Johanas for the USPTO and Stuart A. Nelson for the Applicant. During the interview, the parties discussed differences between the claim language and the cited references. The parties also discussed potential claim amendments. It was agreed that the claims as amended distinguish over the cited references.

# **Specification**

The specification has been amended to address the issues identified by the Examiner regarding paragraphs 0002, 0040, 0041, 0046, and 0055.

# Claim Rejections - 35 USC § 102 and 103

Claims 2, 5-14 were rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Matityahu et al. (US Publication No. 2010/0016903) (referred to as Matityahu). Claims 2-3, 7-14 were rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lieberman (US Publication No. 2003/0181913) (referred to as Lieberman). Claim 3 was rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Matityahu in view of Fanger et al. (US Publication No. 2008/0045951) (referred to as Fanger). Claim 4 was rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Matityahu in view of McGraw et al. (US Publication No. 2008/0033432) (referred to as McGraw).

Without conceding the merits of the rejection but to further prosecution, claim 2 has been amended to require that "the first curved trajectory is along a first single continuous arc" and "the second curved trajectory is along a second single continuous arc." As agreed during the Examiner Interview, these features (particularly as combined with the other features of claim 2)

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are not taught by Matityahu or Lieberman. Accordingly, claim 2 and all claims depending therefrom are patentable over the cited references for at least this reason.<sup>1</sup>

#### Request for Reconsideration

The Applicant respectfully requests prompt consideration and a Notice of Allowance. In the event that no Notice of Allowance will be provided in the next communication, Applicant requests that the Examiner telephone the undersigned attorney (612-337-2538) prior to the next communication so that prosecution on the merits may be expedited. It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendments herein do not signify concession of unpatentability of any claims prior to this amendment. Applicant hereby specifically reserves the right to prosecute the previously presented subject matter in a continuing application. Also, Applicant expressly reserves the right to prosecute claims of different or broader scope in a continuing application. The Patent Office should infer no (i) adoption of a position with respect to patentability, (ii) change in the Applicant's position with respect to any claim or subject matter of the invention, or (iii) acquiescence in any way to any position taken by the Office Action, based on the amendments made herein.

Please apply necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

<sup>1</sup> While Applicant maintains that the claims are patentable for additional reasons as well, this response will focus on the reasons discussed and agreed upon during the May 15, 2018 Examiner Interview.

# Case 2:20-cv-03271-MSG Document 324-3 Filed 11/29/23 Page 158 of 194

First Named Inventor: Nathan C. Moskowitz Attorney Docket: 46440-0013002

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Respectfully submitted,

> Stuart A. Nelson Reg. No. 63,947

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Electronic Acl	knowledgement Receipt
EFS ID:	32641439
Application Number:	15862016
International Application Number:	
Confirmation Number:	6203
Title of Invention:	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER- LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Nathan C. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Abby Remer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	45335-0013002
Receipt Date:	16-MAY-2018
Filing Date:	04-JAN-2018
Time Stamp:	15:07:24
Application Type:	Utility under 35 USC 111(a)

# Payment information:

Submitted wi	th Payment	no			
File Listin	g:				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
			129272		
1		Response.pdf	Sf825ec4400afd610e7408e1c8e8a351da3a 498e	yes	13

	Multipart Description/PDF files in .zip description				
	Document Description	Start	End		
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1		
	Specification	2	4		
	Claims	5	10		
	Applicant Arguments/Remarks Made in an Amendment	11	13		
Warnings:					
Information:					
	Total Files Size (in bytes):	,	129272		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Attorney Docket No.: 46440-0013002

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Nathan C. Moskowitz Art Unit: 3733

Serial No. : 15/862,016 Examiner : Jacqueline T. Johanas

Filed : January 4, 2018 Conf. No. : 6203

Title : HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-

SCREWS WITH INTER-LOCKING RIGID OR JOINTED

FLEXIBLE RODS FOR SPINAL FUSION

# Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# REPLY TO ACTION OF FEBRUARY 21, 2018

Please consider the following reply.

# Case 2:20-cv-03271-MSG Document 324-3 Filed 11/29/23 Page 162 of 194

Attorney Docket: 46440-0013002

First Named Inventor: Nathan C. Moskowitz
Serial No.: 15/862,016
Filed: January 4, 2018
Page: 2 of 3

# Amendments to the Title:

Please replace the Title with the following amended Title:

SPINAL FUSION IMPLANT WITH CURVILINEAR NAIL-SCREWS

 Serial No.
 : 15/862,016

 Filed
 : January 4, 2018

 Page
 : 3 of 3

## **REMARKS**

This Reply supplements the Reply dated 5/16/2018. This Reply is provided to amend the Title to correct spelling errors introduced in the Reply of 5/16/2018.

Apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: <u>5/17/2018</u> /Stuart A. Nelson/

> Stuart A. Nelson Reg. No. 63,947

Customer Number 26191 Fish & Richardson P.C. Telephone: (612) 337-2538 Facsimile: (877) 769-7945

61686274.doc

Electronic Acl	knowledgement Receipt
EFS ID:	32649574
Application Number:	15862016
International Application Number:	
Confirmation Number:	6203
Title of Invention:	HORIZONTAL-TRANSVERTEBRAL CURVILINEAR NAIL-SCREWS WITH INTER- LOCKING RIGID OR JOINTED FLEXIBLE RODS FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Nathan C. Moskowitz
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Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	45335-0013002
Receipt Date:	17-MAY-2018
Filing Date:	04-JAN-2018
Time Stamp:	11:45:05
Application Type:	Utility under 35 USC 111(a)

# Payment information:

Submitted wit	th Payment	no			
File Listin	g:				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
			78908		
1		Response.pdf	5b470c7f998d6fe8653f0310239ca50a3e48 5097	yes	3

	Multipart Description/PDF files in .zip description				
	Document Description	Start	End		
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1		
	Specification	2	2		
	Applicant Arguments/Remarks Made in an Amendment	3	3		
Warnings:					
Information:					
	Total Files Size (in bytes):	7	8908		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

#### New Applications Under 35 U.S.C. 111

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#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



# UNITED STATES PATENT AND TRADEMARK OFFICE

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_	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	15/862,016	01/04/2018	Nathan C. Moskowitz	45335-0013002	6203
		7590 ARDSON P.C. (TC)	8	EXAM	UNER
	PO BOX 1022	`		JOHANAS, JA	CQUELINE T
	MINNEAPOLI	S, MN 55440-1022		ART UNIT	PAPER NUMBER
				3733	***************************************
				NOTIFICATION DATE	DELIVERY MODE
				05/21/2018	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

	Application No.	Applicant(s)			
Applicant-Initiated Interview Summary	15/862,016	MOSKOWITZ ET AL.			
Apprount-initiated interview Juninary	Examiner	Art Unit			
	Jacqueline Johanas	3733			
All participants (applicant, applicant's representative, PTO	personnel):				
(1) Jacqueline Johanas.	(3)				
(2) Stuart Nelson (reg. 63947).	(4)				
Date of Interview: 15 May 2018.					
Type: 🛛 Telephonic 🔲 Video Conference 🔲 Personal [copy given to: 🔲 applicant [	applicant's representative]				
Exhibit shown or demonstration conducted: Yes  If Yes, brief description:	☑ No.				
Issues Discussed 101 112 112 102 103 Other (For each of the checked box(es) above, please describe below the issue and detailed					
Claim(s) discussed: 2.					
Identification of prior art discussed: Matityahu et al. (US Publication No. 2010/0016903 A1), Lieberman (US Publication No. 2003/0181913 A1).					
Substance of Interview (For each issue discussed, provide a detailed description and indicate if agreement reference or a portion thereof, claim interpretation, proposed amendments, argume		entification or clarification of a			
See Continuation Sheet.					
<b>Applicant recordation instructions:</b> The formal written reply to the last O section 713.04). If a reply to the last Office action has already been filed, at thirty days from this interview date, or the mailing date of this interview surrinterview	oplicant is given a non-extendable peri	od of the longer of one month or			
Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.					
Attachment					
/Jacqueline Johanas/ Primary Examiner, Art Unit 3733					
U.S. Patent and Trademark Office PTOL-413 (Rev. 8/11/2010) Interview	v Summary	Paper No. 20180515			

#### **Summary of Record of Interview Requirements**

#### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

# Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- -Type of interview (telephonic, video-conference, or personal)
- -Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by
  attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does
  not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,

(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)

- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

# 

Continuation Sheet (PTOL-413)

Application No. 15/862,016

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Mr. Nelson discussed how Matityahu is only disclosed as a pedicle screw and used through the pedicle whereas Applicant's invention bypasses the pedicle. Examiner maintained that the nail-screw of Matityahu was fully capable of being placed in a different location rather than through the pedicle (e.g. caudally as to avoid the pedicle, at an angle so as to engage the transverse process and then through the vertebral body, etc.) and that the functional claim language reciting avoiding pedicles was insufficient to overcome Matityahu. Mr. Nelson discussed how structurally his nail-screw was different from Matityahu as his nail-screw was "continuously" curved from proximal to distal end while the screw of Matityahu had a straight portion (shown as portion 42 in Fig. 1 of Matityahu). Examiner agreed that this was a structural distinction between the prior art and Applicant's invention.

Mr. Nelson discussed the rejection of claim 2 using the Lieberman reference. Mr. Nelson argued the modification: that one of ordinary skill in the art would not find it obvious to modify the smooth corkscrew with a surface feature such as porous texture because it would impart too much frictional force upon insertion which could damage the patient's tissue and/or hinder insertion of the device. Examiner understood Mr. Nelson's argument however felt that she could provide an evidentiary reference which discusses equivalent modifications in the same field of endeavor/analogous art. Examiner stated that increasing bone ingrowth/preventing back out and overall enhancing security of the implant in the bone was a common motivation in the art for adding such surface features. Further, Examiner stated that porosities allowing bone ingrowth need not be large openings and could be on the scale of micro/nanometers which would not impart much additional friction.

Mr. Nelson brought up the concept that the curved trajectory of extends from the first proximal which contains the head while it appears that in the device of Lieberman, the trajectory ends at the head. Examiner recommended amending the claim to clarify that the first and second trajectories of the first and second curvilinear nail-screws were "single continuous arc" shaped trajectories. This claim limitation would overcome the Matityahu reference as the trajectory of the nail-screw of Matityahu wasn't a "continuous arc" from the proximal to the distal end due to the straight portion and would also overcome the Lieberman reference as the trajectory of the corkscrew shape of Lieberman could not be considered a "single arc" from the proximal to the distal end.

Mr. Nelson stated that he would run this proposed amendment past his client. Examiner invited Mr. Nelson to call back if there was an alternative amendment that was proposed by the client.



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# NOTICE OF ALLOWANCE AND FEE(S) DUE

<sup>26191</sup> 7590 06/18/2018 FISH & RICHARDSON P.C. (TC) PO BOX 1022 MINNEAPOLIS, MN 55440-1022 EXAMINER

JOHANAS, JACQUELINE T

ART UNIT PAPER NUMBER

3733

DATE MAILED: 06/18/2018

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/862,016	01/04/2018	Nathan C. Moskowitz	45335-0013002	6203

TITLE OF INVENTION: SPINAL FUSION IMPLANT WITH CUNVILINEAR NAIL-SCREWS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0	\$0	\$500	09/18/2018

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW

#### HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

Page 1 of 3

#### PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Certificate of Mailing or Transmission 26191 06/18/2018 I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. FISH & RICHARDSON P.C. (TC) PO BOX 1022 MINNEAPOLIS, MN 55440-1022 (Depositor's name (Signature (Date) APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 15/862.016 01/04/2018 Nathan C. Moskowitz 45335-0013002 6203 TITLE OF INVENTION: SPINAL FUSION IMPLANT WITH CUNVILINEAR NAIL-SCREWS APPLN. TYPE ENTITY STATUS ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE **SMALL** \$500 09/18/2018 nonprovisional \$500 \$0 EXAMINER CLASS-SUBCLASS ART UNIT JOHANAS, JACQUELINE T 3733 606-264000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (B) RESIDENCE: (CITY and STATE OR COUNTRY) (A) NAME OF ASSIGNEE Please check the appropriate assignee category or categories (will not be printed on the patent): Individual I 4a. The following fee(s) are submitted: 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) Issue Fee A check is enclosed. Payment by credit card. Form PTO-2038 is attached. Publication Fee (No small entity discount permitted) The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number \_\_\_\_\_\_ (enclose an extra copy of this for Advance Order - # of Copies (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) Applicant certifying micro entity status. See 37 CFR 1.29 NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status. ☐ Applicant asserting small entity status. See 37 CFR 1.27 Applicant changing to regular undiscounted fee status. <u>NOTE:</u> Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable. NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications

Page 2 of 3

Date

Registration No.

Authorized Signature

Typed or printed name



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FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. 15/862,016 01/04/2018 Nathan C. Moskowitz 45335-0013002 6203 EXAMINER 06/18/2018 26191 7590 FISH & RICHARDSON P.C. (TC) JOHANAS, JACQUELINE T PO BOX 1022 ART UNIT PAPER NUMBER MINNEAPOLIS, MN 55440-1022 3733

DATE MAILED: 06/18/2018

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

#### OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## **Privacy Act Statement**

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

	Application No.	Applicant(s)	
	15/862,016	MOSKOWITZ	
Notice of Allowability	Examiner	Art Unit	AIA (First Inventor to File)
induction of Amonability	Jacqueline Johanas	3733	Status
			No
The MAILING DATE of this communication appeared in the series allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R	(OR REMAINS) CLOSED in this ap or other appropriate communicatio IGHTS. This application is subject to	plication. If not n will be mailed	included in due course. <b>THIS</b>
This communication is responsive to <u>amendment filed 05/10</u> A declaration(s)/affidavit(s) under <b>37 CFR 1.130(b)</b> was			
An election was made by the applicant in response to a rest requirement and election have been incorporated into this a		the interview or	1; the restriction
3. The allowed claim(s) is/are <u>2-24</u> . As a result of the allowed Highway program at a participating intellectual property offinhttp://www.uspto.gov/patents/init_events/pph/index.jsp or se	ce for the corresponding application	ı. For more info	
4. Acknowledgment is made of a claim for foreign priority unde	er 35 U.S.C. § 119(a)-(d) or (f).		
Certified copies: a) ☐ All b) ☐ Some *c) ☐ None of the:			
<ul> <li>a) ☐ All b) ☐ Some *c) ☐ None of the:</li> <li>1. ☐ Certified copies of the priority documents have</li> </ul>	haan racaivad		
<ol> <li>Certified copies of the priority documents have</li> </ol>			
Copies of the certified copies of the priority do			annlication from the
International Bureau (PCT Rule 17.2(a)).	cuments have been received in this	national stage	аррисацон пош ше
* Certified copies not received:			
Certified copies not received			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		complying with	the requirements
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") mus	t be submitted.		
including changes required by the attached Examiner's Paper No./Mail Date		Office action of	
Identifying indicia such as the application number (see 37 CFR 1	.84(c)) should be written on the draw	ings in the front	(not the back) of
each sheet. Replacement sheet(s) should be labeled as such in t 6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of E attached Examiner's comment regarding REQUIREMENT FC	he header according to 37 CFR 1.121 BIOLOGICAL MATERIAL must be si	( <b>d).</b> ubmitted. Note i	
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5. ⊠ Examiner's Amend	ment/Comment	
2. Information Disclosure Statements (PTO/SB/08),	6. ☑ Examiner's Statem		
Paper No./Mail Date			ior i morranio
3. Examiner's Comment Regarding Requirement for Deposit	7. 🔲 Other		
of Biological Material 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date			
/Jacqueline Johanas/ Primary Examiner, Art Unit 3733			

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13)

Notice of Allowability

Part of Paper No./Mail Date 20180607

Application/Control Number: 15/862,016

Art Unit: 3733

The present application is being examined under the pre-AIA first to invent provisions.

#### **EXAMINER'S COMMENT**

Amendments to the specification filed 05/16/2018 have been entered.

Amendment to the title filed 05/17/2018 changing the title to "SPINAL FUSION IMPLANT WITH CURVILINEAR NAIL-SCREWS" has been entered.

#### Election/Restrictions

Claim 2 is directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 15-21, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on 02/21/2018 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the

Page 2

Application/Control Number: 15/862,016

Page 3

Art Unit: 3733

provisions of 35 U.S.C. 121 are no longer applicable. See In re Ziegler, 443 F.2d 1211,

1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

REASONS FOR ALLOWANCE

See examiner's statements in interview summary mailed 02/21/2018 for reasons

for allowance.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Jacqueline Johanas whose telephone number is

(571)270-5085. The examiner can normally be reached on Monday to Friday, 9:00am

to 5:00pm.

Examiner interviews are available via telephone, in-person, and video

conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request

(AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

MOSKOWITZ-00000175

Application/Control Number: 15/862,016 Page 4

Art Unit: 3733

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline Johanas/ Primary Examiner, Art Unit 3733

### **EAST Search History**

# **EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	88	(nathan near2 moskowitz).in.	US-PGPUB; USPAT; EPO	OR	ON	2018/06/07 19:06
L2	89	(mosheh near2 moskowitz).in.	US-PGPUB; USPAT; EPO	OR	ON	2018/06/07 19:06
L3	73	(ahmnon near2 moskowitz).in.	US-PGPUB; USPAT; EPO	OR	ON	2018/06/07 19:06
L4	8331	a61b17/7001-7046.cpc.	US-PGPUB; USPAT	OR	ON	2018/06/07 19:06
L5	287	a61b17/7056.cpc.	US-PGPUB; USPAT	OR	ON	2018/06/07 19:06
L6	677	a61b17/7053.cpc.	US-PGPUB; USPAT	OR	ON	2018/06/07 19:06
L7	4095	a61b17/8625,86.cpc.	US-PGPUB; USPAT	OR	ON	2018/06/07 19:06
L8	736	a61b2017/8655.cpc.	US-PGPUB; USPAT	OR	ON	2018/06/07 19:06
L9	12546	L4 L5 L6 L7 L8	US-PGPUB; USPAT	OR	ON	2018/06/07 19:06

# **EAST Search History (Interference)**

Ref	Hits	Search Query		Default Operator	Plurals	Time Stamp
L10		(spinal and fusion and curvilinear and nail\$1screw and arc and hole and connecting and means).clm.	US- PGPUB	OR	10	2018/06/07 19:10

6/7/2018 7:11:11 PM

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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	15862016	MOSKOWITZ ET AL.
	Examiner	Art Unit
	JACQUELINE JOHANAS	3733

CPC- SEARCHED								
Symbol	Date	Examiner						
a61b17/7001-7046,7056,7053,8625,86	2/14/2018	JJ						
a61b2017/8655	2/14/2018	JJ						
above updated	6/7/2018	JJ						

CPC COMBINATION SETS - SEARCHED								
Symbol	Date	Examiner						

	US CLASSIFICATION SEA	ARCHED	
Class	Subclass	Date	Examiner

<sup>\*</sup> See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

SEARCH NOTES								
Search Notes	Date	Examiner						
EAST, inventor searches	2/14/2018	JJ						
above updated	6/7/2018	JJ						

INTERFERENCE SEARCH									
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner						
	PGPUB Database, see printout	6/7/2018	JJ						

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Part of Paper No.: 20180607

	Application/Control No.	Applicant(s)/Patent Under Reexamination		
Index of Claims	15862016	MOSKOWITZ ET AL.		
	Examiner	Art Unit		
	JACQUELINE JOHANAS	3733		

1	Rejected	***	Cancelled	N	Non-Elected	Α	Appeal
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Final	Original	02/14/2018	06/07/2018							
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Part of Paper No.: 20180607

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	15862016	MOSKOWITZ ET AL.
	Examiner	Art Unit
	JACQUELINE JOHANAS	3733

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A61F	2220	7 0025	A	2013-01-01
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A61B	2017	7 0648	A	2013-01-01
A61B	2017	7 0647	A	2013-01-01
A61B	2017	/ 0641	A	2013-01-01
A61B	17	/ 8685		2013-01-01
A61B	17	/ 8625	!	2013-01-01
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A61B	17	7023		2013-01-01
A61B	17	/ 7011	!	2013-01-01
A61B	17	/ 7004		2013-01-01
A61B	17	/ 7001	!	2013-01-01
A61B	17	/ 068	!	2013-01-01
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CPC Combination Sets										
Symbol	Туре	Set	Ranking	Version						

NONE		Total Clain	ns Allowed:
(Assistant Examiner)	(Date)	2	3
/JACQUELINE JOHANAS/ Primary Examiner.Art Unit 3733	06/07/2018	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	2	8A

U.S. Patent and Trademark Office Paper No. 20180607

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	15862016	MOSKOWITZ ET AL.
	Examiner	Art Unit
	JACQUELINE JOHANAS	3733

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/JACQUELINE JOHANAS/ Primary Examiner.Art Unit 3733	06/07/2018	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	2	8A

U.S. Patent and Trademark Office Paper No. 20180607

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	15862016	MOSKOWITZ ET AL.
	Examiner	Art Unit
	JACQUELINE JOHANAS	3733

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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NONE		Total Clain	ns Allowed:
(Assistant Examiner)	(Date)	2	3
/JACQUELINE JOHANAS/ Primary Examiner.Art Unit 3733	06/07/2018	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	2	8A

U.S. Patent and Trademark Office Paper No. 20180607

Attorney's Docket No.: 46440-0013002

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Nathan C. Art Unit

Examiner : Jacqueline T. Johanas

Moskowitz : 15/862,016 Application No. Confirmation No. : 6203

Notice of Allowance Date: June 18, 2018 Filed : January 4, 2018

SPINAL FUSION IMPLANT WITH CURVILINEAR NAIL-Title

**SCREWS** 

# MAIL STOP ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# REPLY TO NOTICE OF ALLOWANCE

In response to the Notice of Allowance dated June 18, 2018, enclosed is a completed Part B - Fee(s) Transmittal.

The issue fee is being paid with this reply on the Electronic Filing System. Apply those fees and any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: <u>6/20/2018</u> /Stuart A. Nelson/

> Stuart A. Nelson Reg. No. 63,947

Customer Number 26191 Fish & Richardson P.C. Telephone: (612) 337-2538

Facsimile: (877) 769-7945

61705673.doc

# PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the

26191 7590 FISH & RICHARDSO P.O. BOX 1022 MINNEAPOLIS, MN 5		/2018		pape have I her State addr	rs. Each additional tits own certificate Cer reby certify that thi es Postal Service w essed to the Mail	paper of mai tificate is Fee( ith suf Stop	, such as an assignment ling or transmission. e of Mailing or Transm s) Transmittal is being (	deposited with the United class mail in an envelope bove, or being facsimile			
								(Depositor's name)			
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APPLICATION NO.	FILING DATE			FIRST NAMED INVENTOR	TENTOR ATTORNEY DOCKET NO. CONFIRMATION NO.						
15/862,016	01/04/2018			Nathan C. Moskowitz		4	6440-0013002	6203			
TITLE OF INVENTION: SP	INAL FUSION IMPLAN	WITH CURVIL	NEAR N	VAIL-SCREWS							
APPLN, TYPE	ENTITY STATUS	ISSUE FEE I	UE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE	TOTAL FEE(S) DUE	DATE DUE			
nonprovisional	SMALL	\$500		\$0			\$500	09/18/2018			
EXAMIN	ER	ART UNI	 Г	CLASS-SUBCLASS							
JOHANAS, JAC	QUELINE T.	3733		606-264000	•						
1. Change of corresponder	nce address or indicatio	n of "Fee Addre	ss" (37	2. For printing on the p	atent front page, lis	st					
CFR 1.363).		inge of Correspo	ndence	(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  1 Fish & Richardson P.C.							
Address form PTO/SB/ [ ] "Fee Address" indic PTO/SB/47; Rev 03-02 Number is required.	cation (or "Fee Address	(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.									
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(A) NAME OF ASSIGN Moskowitz Family				(B) RESIDENCE: (CIT Rockville, MD	B) RESIDENCE: (CITY and STATE OR COUNTRY) Rockville, MD						
Please check the appropriate assignee category or categories (will not be printed on the patent): [ ] Individual [X] Corporation or other private group entity [ ] Gov  4a. The following fee(s) are submitted:  [X] Issue Fee [ ] A check in the amount of the fee(s) is enclosed.  [ ] Publication Fee (No small entity discount permitted)  [ ] Advance Order - # of Copies  [ X] The Director is hereby authorized to charge the required fee(s), or credit any overpayn  Deposit Account Number 06-1050							nown above)				
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The Director of the USPTC NOTE: The Issue Fee and in interest as shown by the	Publication Fee (if requ	ired) will not be	accepte	ed from anyone other than							
Authorized Signature /	Stuart A. Nelson/				Date 6/20/20	018					
Typed or printed name	Stuart A. Nelson				Registration No	o. <u>6</u>	3,947				

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Filing Date:  O4-Jan-2018  Title of Invention:  SPINAL FUSION IMPLANT WITH CUNVILINEAR NAIL-SCREWS  First Named Inventor/Applicant Name: Nathan C. Moskowitz  Filer: Stuart A. Nelson/Abby Remer  Attorney Docket Number: 45335-0013002  Filled as Small Entity  Filling Fees for Utility under 35 USC 111(a)  Description Fee Code Quantity Amount Sub-Total in USD(s)  Basic Filing: Pages:	Electronic Patent Application Fee Transmittal										
Title of Invention:  SPINAL FUSION IMPLANT WITH CUNVILINEAR NAIL-SCREWS  First Named Inventor/Applicant Name:  Nathan C. Moskowitz  Filer:  Stuart A. Nelson/Abby Remer  Attorney Docket Number:  45335-0013002  Filed as Small Entity  Filing Fees for Utility under 35 USC 111(a)  Description  Fee Code  Quantity  Amount  Sub-Total in USD(\$)  Basic Filing:	Application Number:	15862016									
First Named Inventor/Applicant Name:  Nathan C. Moskowitz  Filer:  Stuart A. Nelson/Abby Remer  Attorney Docket Number:  45335-0013002  Filed as Small Entity  Filing Fees for Utility under 35 USC 111(a)  Description  Fee Code  Quantity  Amount  Sub-Total in USD(\$)	Filing Date:	04-Jan-2018									
Filer: Stuart A. Nelson/Abby Remer  Attorney Docket Number: 45335-0013002  Filed as Small Entity  Filing Fees for Utility under 35 USC 111(a)  Description Fee Code Quantity Amount Sub-Total in USD(\$)  Basic Filing:	Title of Invention:										
Attorney Docket Number: 45335-0013002  Filed as Small Entity  Filing Fees for Utility under 35 USC 111(a)  Description Fee Code Quantity Amount Sub-Total in USD(\$)  Basic Filing:	First Named Inventor/Applicant Name:	Nathan C. Moskowitz									
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Pages:	Basic Filing:										
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Claims:	Claims:										
Miscellaneous-Filing:	Miscellaneous-Filing:										
Petition:											
Patent-Appeals-and-interference:	Patent-Appeals-and-Interference:										
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# Case 2:20-cv-03271-MSG Document 324-3 Filed 11/29/23 Page 187 of 194

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)	
Extension-of-Time:					
Miscellaneous:					
	Total in USD (\$)		(\$)	500	

Electronic Acknowledgement Receipt				
EFS ID:	32951236			
Application Number:	15862016			
International Application Number:				
Confirmation Number:	6203			
Title of Invention:	SPINAL FUSION IMPLANT WITH CUNVILINEAR NAIL-SCREWS			
First Named Inventor/Applicant Name:	Nathan C. Moskowitz			
Customer Number:	26191			
Filer:	Stuart A. Nelson/Natalie Reynolds			
Filer Authorized By:	Stuart A. Nelson			
Attorney Docket Number:	45335-0013002			
Receipt Date:	20-JUN-2018			
Filing Date:	04-JAN-2018			
Time Stamp:	14:47:43			
Application Type:	Utility under 35 USC 111(a)			

# Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$500
RAM confirmation Number	062118INTEFSW00001101061050
Deposit Account	
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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.
		131050			
1	Issue Fee Payment (PTO-85B)	Issue Fee.pdf	c889e4fcfc1fc698a65fff637dddb25686067f b4	no	2
Warnings:	L		<u> </u>		••••••
Information:					
			30287		
2	Fee Worksheet (SB06)	fee-info.pdf	4945db57c78a888c2ac06c0511b941c11d7 43024	no	2
Warnings:	<u> </u>		<b></b>		
Information:					
		Total Files Size (in bytes)	16	51337	

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## New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS Post 1450 Alexandria, Virginia 22313-1450 www.uspio.gov

FILING or GRPART FIL FEE REC'D FOT CLAIMS IND CLAIMS NUMBER 371(c) DATE UNIT ATTY.DOCKET.NO 15/862,016 01/04/2018 3733 730 45335-0013002 20

26191 FISH & RICHARDSON P.C. (TC) PO BOX 1022 MINNEAPOLIS, MN 55440-1022

**CONFIRMATION NO. 6203 CORRECTED FILING RECEIPT** 

Date Mailed: 06/25/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections

Inventor(s)

Nathan C. Moskowitz, Rockville, MD; Mosheh T. Moskowitz, Rockville, MD; Ahmnon D. Moskowitz, Rockville, MD;

Applicant(s)

Nathan C. Moskowitz, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 26191

# Domestic Priority data as claimed by applicant

This application is a CON of 12/957,776 12/01/2010 PAT 9888918 which is a CIP of 12/471,340 05/22/2009 PAT 8734516 which is a CIP of 12/054,335 03/24/2008 PAT 7972363

which is a CIP of 11/842,855 08/21/2007 PAT 7942903

which is a CIP of 11/536,815 09/29/2006 PAT 7846188 which is a CIP of 11/208,644 08/23/2005 PAT 7704279

and said 12/957,776 12/01/2010 claims benefit of 60/670,231 04/12/2005

and claims benefit of 61/265,752 12/01/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see <a href="http://www.uspto.gov">http://www.uspto.gov</a> for more information.) - None. Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

page 1 of 4

#### Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

#### If Required, Foreign Filing License Granted: 01/26/2018

The country code and number of your priority application, to be used for filing abroad under the Paris Convention,

is US 15/862,016

Projected Publication Date: Not Applicable

Non-Publication Request: No Early Publication Request: No

\*\* SMALL ENTITY \*\*

Title

SPINAL FUSION IMPLANT WITH CURVILINEAR NAIL-SCREWS

**Preliminary Class** 

606

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, page 2 of 4

this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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 APPLICATION NO.
 ISSUE DATE
 PATENT NO.
 ATTORNEY DOCKET NO.
 CONFIRMATION NO.

 15/862,016
 07/24/2018
 10028740
 45335-0013002
 6203

26191 7590 07/04/2018

FISH & RICHARDSON P.C. (TC) PO BOX 1022 MINNEAPOLIS, MN 55440-1022 UNITED STATES OF AMERICA

# **ISSUE NOTIFICATION**

The projected patent number and issue date are specified above.

# **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

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Nathan C. Moskowitz, Rockville, MD;

Mosheh T. Moskowitz, Rockville, MD;

Ahmnon D. Moskowitz, Rockville, MD;

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